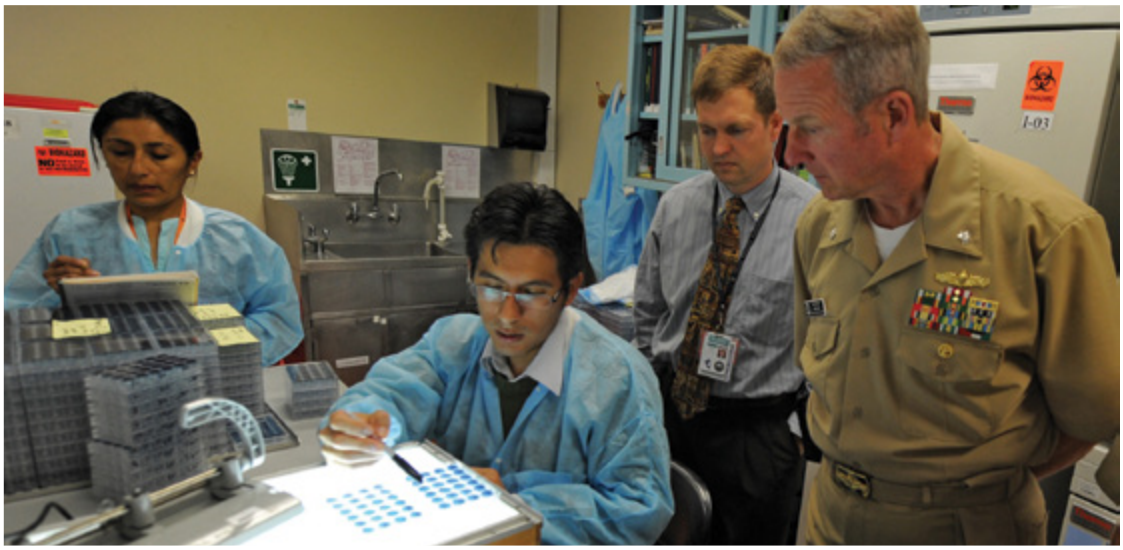
VA/DoD Collaboration Guidebook for Healthcare Research · 2013



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Cover Photos:

Top: Norbert Schuff, PhD, and Monica Camacho review MRI brain scans at the San Francisco VA Medical Center. (Photo by Roy Kaltschmidt)

Middle: A Peruvian lab technician, second from left, explains antibody testing procedures to U.S. Naval Medical Research Unit (NMRU) 6 commanding officer Capt. John Sanders, third from left, and Navy Cmdr. Mark Becker, right, mission commander of Southern Partnership Station 2011, during a tour of the NMRU compound in Lima, Peru. (Photo by Mass Communication Specialist 1st Class Jeffery Tilghman Williams)

Bottom Left: Former Marine Carlos Macias reviews a liver-biopsy image with Kenneth Cusi, MD, at the San Antonio VA. Dr. Cusi, today at the Gainesville (Fla.) VA, studies type 2 diabetes and nonalcoholic fatty liver disease, particularly in Hispanics.

Bottom Right: Fred Downs Jr., former chief of prosthetics and sensory aids for VA, wears the DEKA prosthetic arm as he chats with Col. Geoffrey Ling of the Defense Advanced Research Projects Agency (DARPA). The arm was developed by DEKA Integrated Solutions Corporation under DARPA's Revolutionizing Prosthetics program. VA has been studying it with the help of Veteran volunteers and collaborating with DEKA and DARPA on its optimization.

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This guidebook is a compilation of material from multiple sources, including publicly available websites and documents. We acknowledge the many individuals who contributed to the revision of this guidebook by serving on our advisory group, providing input to the guidebook, and reviewing specific content areas. Some of these contributors also assisted with the 2011 edition of the guidebook. Many thanks to the 2011 contributors who are not acknowledged below.

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Disclaimer

The opinions and assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of Veterans Affairs, the departments of the Army, Navy, or Air Force, or the Department of Defense.

To the best of our knowledge, the information in this guidebook is current as of August 30, 2013.

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U.S. Navy Lt. Andrea McCoy prepares a sample for testing in the medical laboratory aboard the hospital ship USNS Comfort (T-AH 20) in San Juan del Sur, Nicaragua, during Continuing Promise 2011. Continuing Promise was a five-month humanitarian assistance mission to countries in the Caribbean, Central and South America. (Photo by Senior Airman Kasey Close)

Section I: Overview

1. Purpose of the Guidebook

The purpose of this guidebook is to help facilitate collaborative human subject healthcare research between the Department of Veterans Affairs (VA) and the Department of Defense (DoD). The guidebook provides researchers with an introduction to collaboration and the information needed to more effectively identify and partner with others who have common research interests. It provides research administrators with information and resources to more effectively assist their investigators in planning and implementing collaborative projects. It also serves as a resource for scientific program managers and project officers.

Intended Audience:

VA and DoD human subject healthcare researchers, clinician-investigators, research administrators, scientific program managers, and project officers

Suggested Uses:

Planning for initiation and administration of collaborative research efforts

This guidebook identifies the types, benefits, and challenges of interagency research collaboration and provides resources to identify ongoing research efforts. Each department's administrative and funding mechanisms are summarized, and procedures and protocols that VA and DoD researchers need to follow in their collaborative efforts are introduced.

The guidebook gives suggestions for seeking a collaborator; planning, crafting, and submitting a proposal; and formalizing the collaboration. In addition, it provides examples of successful research collaborations and the challenges faced in the process, a list of commonly used acronyms (Appendix A), and links to additional resources including links to templates and sample documents for both VA and DoD (Appendix B). It contains tips from experienced researchers on how to maximize available resources and provides recommendations for future consideration. We hope readers of this guidebook will find it valuable in their collaborative research efforts for the continuing benefit of our Service members, Veterans, and both healthcare systems.

a. VA/DoD Collaborations

Over the past 20 years, there have been numerous legislative efforts to encourage and increase collaboration between VA and DoD, covering issues from the construction of military and VA healthcare facilities[i] to the sharing of electronic medical records and technology transfer[ii].

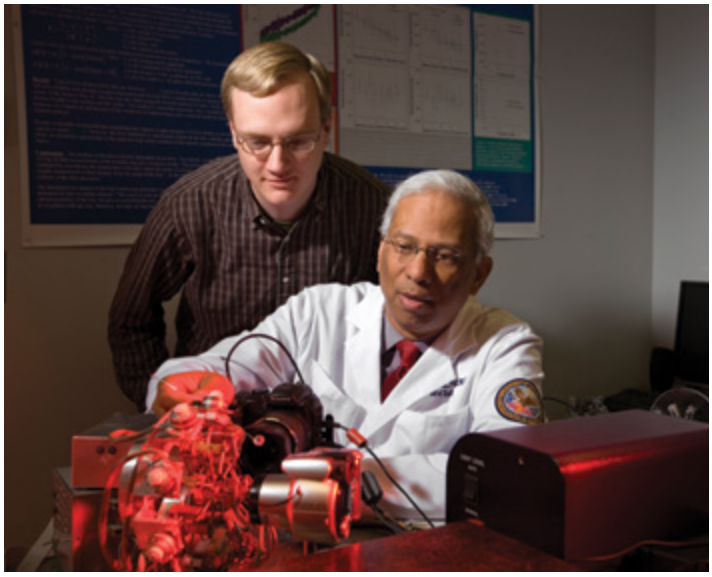
Many formal studies have been conducted to improve clinical and administrative collaboration between agencies. There are currently multiple VA/DoD executive councils, coordinating offices, and working groups.

In FY2012, there were 230 direct sharing agreements between 61 VA medical centers (VAMCs) and 105 DoD medical facilities. This research collaboration guidebook is part of this ongoing effort.

b. What is Research Collaboration?

In research, collaboration ranges from offering advice or networking assistance to active partnership in all aspects of a research project. All efforts across that continuum are similar in that researchers work together to achieve the shared goal of producing new scientific knowledge.

The basic unit of collaboration is the cooperative relationship between two or more researchers. This guidebook focuses on collaborative efforts between



Engineer Paul Hamilton (standing) and ophthalmologist Nathan Ravi, chief of staff at the St. Louis VA, collaborated to build a robotic "lens stretcher" that mimics the function of the ciliary muscle inside the human eye. (Photo by Jerry Naunheim Jr.)

human subject healthcare researchers and clinicians working in VA and DoD. VA-DoD research partnerships involve collaboration between individuals or teams from both departments, each with knowledge of and experience with the people, priorities, and practices of their respective department. These partnerships take many forms and involve various personnel, depending on the scope of the project. There are both civilian and military researchers within DoD and VA participating in research collaborations.

Research can also be conducted by a researcher from one department in partnership with clinical investigators, clinicians with a scholarly interest, or medical command personnel from the other department. Clinician involvement is important to ensure that study implementation is grounded in clinical practice; is in line with departmental and facility policies, priorities, and practices; and can be translated to benefit Service members and Veterans. Researcher involvement is equally crucial to make certain that the study has sound scientific design, protects human subjects, uses appropriate analytical methods, and is disseminated into the scientific literature.

At its foundation, collaboration means building cooperative, respectful, and trusting individual relationships with one another for mutual benefit. As the complex work of building stronger overall collaborative relationships between the departments progresses, individual research relationships can highlight the benefits of collaboration and overcome the challenges associated with the collaborative process.

2. Why Collaborate?

As Figure 1 illustrates, researchers choose to collaborate for various reasons: to answer research questions that are most effectively addressed through collaborative studies; to share responsibility, expertise, or perspective; to pool financial and human resources; to increase efficiency and funding opportunities; or to gain greater credibility.

A military collaborator understands the military culture and can offer strategies for building liaisons with and obtaining permissions from the appropriate command or military agency. Similarly, a VA collaborator understands the working structure and culture of VA.

Finally, a key reason for DoD and VA researchers to collaborate is to enable longitudinal studies of Service members and Veterans that encompass diagnosis, course of treatment, outcomes, and impact on family.

Figure 1. Reasons to Collaborate

a. Benefits and Challenges

While collaborative efforts may present unique challenges, such as hiring and credentialing staff, and guiding collaborators with less research experience through the process, this partnership of perspectives and skill sets can increase the likelihood of success and translation of research results into practice. Keep in mind that research collaborations may be supported by intramural or extramural funds, or some combination thereof. As such, prior to the initiation of a collaborative effort, investigators need to consider differences in how the departments fund research.

As mentioned earlier, there are many benefits to health-related research collaborations between VA and DoD. The agencies serve a similar population, although usually at different times in the military life cycle. For example, DoD provides healthcare for active duty Service members, their dependents, and retirees from all branches of the military and their families, while VA provides healthcare benefits to qualified Veterans, including deactivated Reserve Component Service members, and in some instances, active duty Service members.

Clinicians and researchers from VA and DoD have many common interests. Because of this, cross-agency research collaborations have the potential to benefit Service members, Veterans, and both healthcare systems.

While the benefits of collaboration are clear, there are also multiple challenges to interagency collaboration. For example:

- Each department has a different set of policies and procedures governing research; it may take many months for a project to receive all required approvals.
- Each agency has its own credentialing and training requirements. If these requirements are not considered in the early stages of project planning, there can be unplanned delays getting research staff on board.
- Continuity of staff and research subjects at DoD institutions can be a challenge, as active duty Service members (which may include key study personnel) may be deployed or reassigned to another location during a study.
- Changes in base commanders and other high-ranking staff may lead to changes in research priorities and the reduction of support for ongoing projects.
- Agencies have unique security processes to access Service member and Veteran data. See Section II.6.a. for details.
- Access to and availability of necessary facilities, including laboratory and office space, and information technology support may be limited.
- In DoD military treatment facilities (MTFs), protected research time is approved on a local command basis only. In VA, there are funding mechanisms (e.g., career development and career scientist programs) to allow scientists protected research time. In addition, clinicians, per agreement with the medical center director, may be allowed protected research time.

These challenges and suggestions for addressing them will be discussed later in this guidebook.

3. Identifying Ongoing Research Efforts

Before research collaboration is initiated, it is helpful to identify related research that has been conducted or is currently under way. A natural place to start is a literature search to identify previously published work. PubMed can be used to identify past research conducted by DoD or VA researchers. It is more challenging to locate planned or ongoing studies and identify potential collaborators, even though, at any given time, there are numerous ongoing research projects in both VA and DoD. Some suggested resources to search or contact are included in Tables 1, 2, and 3.

a. DoD/VA Centers of Excellence (CoEs)

Congress enacted a center of excellence model to organize research and clinical efforts around highly prevalent and serious war-related injuries. A center of excellence oversight board was established under the Assistant Secretary of Defense for Health Affairs to guide the establishment of such centers and provide support. The four congressionally mandated CoEs are the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury,[1] the Vision Center of Excellence[2] (VCE), the Hearing Center of Excellence[3] (HCE), and the Extremity Trauma and Amputation Center of Excellence[4] (EACE). These CoEs are unique in that they have responsibility to improve care and research throughout the continuum of care, from prevention and diagnosis through treatment, mitigation, rehabilitation, and restoration. They are required to develop registries to identify and track injuries. Such efforts cross lanes with many of the research sponsorship responsibilities of the Services, VA, and the National Institutes of Health (NIH). The centers have a unique opportunity and mandate to integrate with research communities to provide transparency across the specialty and translational framework to assist in the planning, prioritization, and translation of early research efforts back into the clinic and field. Other CoEs exist to address disease-specific or Service-specific functions without a comprehensive congressional mandate. More information about joint CoEs can be found in Tables 3 and 4.

1. www.dcoe.health.mil
2. vce.health.mil
3. hearing.health.mil
4. www.bamc.amedd.army.mil/departments/orthopaedic/cfi

Table 1. General and VA Research Resources

WEBSITE OR SOURCE	DESCRIPTION
General Resources for Clinical Trials	
www.ClinicalTrials.gov	ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world.
www.centerwatch.com	CenterWatch provides a registry of clinical trials available for search, along with training information.
VA Research Resources	
www.hsrd.research.va.gov/research	Within VA, all Health Services Research & Development (HSR&D)-funded projects can be found on this website, sorted by project status (e.g., newly funded, current, completed), designated research area (DRA), designated research element (DRE), portfolio (e.g., mental health, long-term care), and research center.
RDIS database	The Research and Development Information System (RDIS), which includes the Web-based ePromise, is a VA database of all researchers and research projects. You may need to contact your local VA administrative officer to access this database.
art.puget-sound.med.va.gov (VA Intranet)	The Annual Report Template (ART) program is an automated reporting system that gathers, tracks, and organizes personnel, funding, and project data from VA HSR&D centers and all Office of Research and Development (ORD) clinical trials. Only VA personnel logged into the VA network can access the ART website and database.
www.research.va.gov/resources/pubs	This site makes available VA annual reports from 1997-2003 and may be another source to learn about VA research efforts. Other points of contact for these reports include portfolio managers in HSR&D and Rehabilitation Research and Development (RR&D).
VA liaisons in Military Treatment Facilities (MTFs)	VA liaisons are VA employees within MTFs such as the Defense and Veterans Brain Injury Center and the National Intrepid Center of Excellence (NICOE) who can serve as a resource to researchers.
www.research.va.gov/programs/csp	The VA Cooperative Studies Program (CSP) is the division of VA R&D that is responsible for the planning and conduct of large multicenter clinical trials and epidemiological studies in VA.
www.hsrd.research.va.gov/coin	VA HSR&D is providing five-year core funding to 19 Centers of Innovation (COINs). COINs will reward research innovations and partnerships to ensure that research has the greatest possible impact on VHA policies, healthcare practices, and health outcomes for Veterans. A unique feature of the COINs is that they include one or more focused areas of research that address questions of significance to VHA clinical and operational partners, and these partners will be engaged in the research activities of the COINs. Each COIN is affiliated with one or more VA medical centers and collaborates with local schools of public health and other university resources.

Table 2. DoD Research Resources

WEBSITE OR SOURCE	DESCRIPTION
DoD Research Resources	
www.dtic.mil/dtic/search/tr/tr.html	The Defense Technical Information Center (DTIC) site has links for research funded through DoD.
cdmrp.army.mil	DoD's Congressionally Directed Medical Research Programs (CDMRP) website.
www.usuhs.mil/tsnrp/GrantApplications/callforproposals.php	The TriService Nursing Research Program (TSNRP) funds and supports rigorous scientific research in the field of military nursing to advance nursing science and optimize the health of military members and their families.
www.tatrc.org	The Telemedicine & Advanced Technology Research Center (TATRC) lists Congressional programs managed by the Army. TATRC program officers can be used as resources.
www.darpa.mil	The Defense Advanced Research Projects Agency (DARPA) funds unique and innovative research through the private sector and academic and nonprofit organizations, as well as government labs.
fhpr.dhhq.health.mil/dmrn.aspx	The Defense Medical Research Network (DMRN). Access only with CAC or PKI card.
www.capmed.mil/about	Informational site about the National Capital Region Medical Directorate (NCRMD).
Army Research Resources	
www.arl.army.mil/www	The U.S. Army Research Laboratory (ARL) of the U.S. Army Research Development and Engineering Command (RDECOM) is the Army's corporate, or central, laboratory.
mrmc.amedd.army.mil	This Medical Research and Materiel Command (MRMC) site provides information and links to all Army medical research laboratories, institutes, and centers worldwide. The research area directorates (RADs) are a resource on programs. CDMRP and TATRC, listed above, are also part of MRMC.
Navy Research Resources	
www.onr.navy.mil	The Office of Naval Research (ONR) coordinates, executes, and promotes the science and technology programs of the U.S. Navy and Marine Corps. Its mission is to plan, foster, and encourage scientific research that relates to the maintenance of future naval power and the preservation of national security.
www.med.navy.mil/sites/nmrc	The Naval Medical Research Center (NMRC) is the Navy's lead medical research and development laboratory. The NMRC and its subordinate laboratories around the world enhance the health, safety, readiness, and performance of Navy and Marine Corps personnel through basic and applied biomedical research. Its labs are listed in Section II and the Appendix section.
www.med.navy.mil/sites/nmrc/Pages/admin_amdpo.htm	The Advanced Medical Development (AMD) Program Office is the materiel developer for the Bureau of Medicine and Surgery. The AMD Program Office manages and coordinates the business and scientific research of advanced medical devices and their development through the project life cycle. Its mission is to promote, protect, and maintain the health of personnel in Navy Medicine, as well as support medical readiness through advanced biomedical research.

(continued on next page)

Table 2. DoD Research Resources (continued)	
Air Force Research Resources	
www.wpafb.af.mil/afrl/afosr	The Air Force Office of Scientific Research (AFOSR) manages the basic research investment for the U.S. Air Force.
www.whasc.af.mil	The 59th Medical Wing Chief Scientist's Office (59 MDW/ST) provides direction, oversight, project management support, and technical resources to advance medical modernization efforts, with a unique focus on clinical and translational research and development activities.
www.federallabs.org/labs/profile/?id=2201 kx.afms.mil	The U.S. Air Force Medical Service Office of Research and Technology Applications (AFMS ORTA) serves as the focal point for clinical research technology transfer by supporting translation of clinical research into practice, and facilitating AFMS clinical researchers' collaborations with industry, academia, and local, state, and federal agencies.
kx.afms.mil/clinicalinvestigations	The Clinical Investigation Program (CIP) aims to improve the quality of health care for DoD beneficiaries by generating an atmosphere of scientific inquiry, promoting an academic environment of high professional standing, and providing a means to assist in the accreditation of graduate medical education and other allied health training programs. The CIP is governed primarily by DoDI 6000.08, "Funding and Administration of Clinical Investigation Programs."

Table 3. DoD/VA Centers of Excellence Research Resources	
WEBSITE OR SOURCE	DESCRIPTION
DoD/VA CoEs	
www.dcoe.health.mil	Defense Center of Excellence for Psychological Health (PH) and Traumatic Brain Injury (TBI) (DCoE), including National Intrepid Center of Excellence (NICoE) for PH and TBI and the Defense and Veterans Brain Injury Center (DVBIC)
vce.health.mil	Department of Defense Vision Center of Excellence (VCE)
hearing.health.mil	Department of Defense Hearing Center of Excellence (HCE)
www.bamc.amedd.army.mil/departments/orthopaedic/cfi	Department of Defense Extremities and Amputees Center of Excellence (EACE)

Table 4. DoD/VA CoEs General Information				
CoE	ESTABLISHED	SERVICE	HQ	RESPONSIBILITY
DCoE	2007	USA	MD	PTSD, TBI
VCE	2008	USN	MD	Eye injury
HCE	2009	USAF	San Antonio, TX	Hearing loss, auditory system injury
EACE	2009	USA	San Antonio, TX	Amputee care

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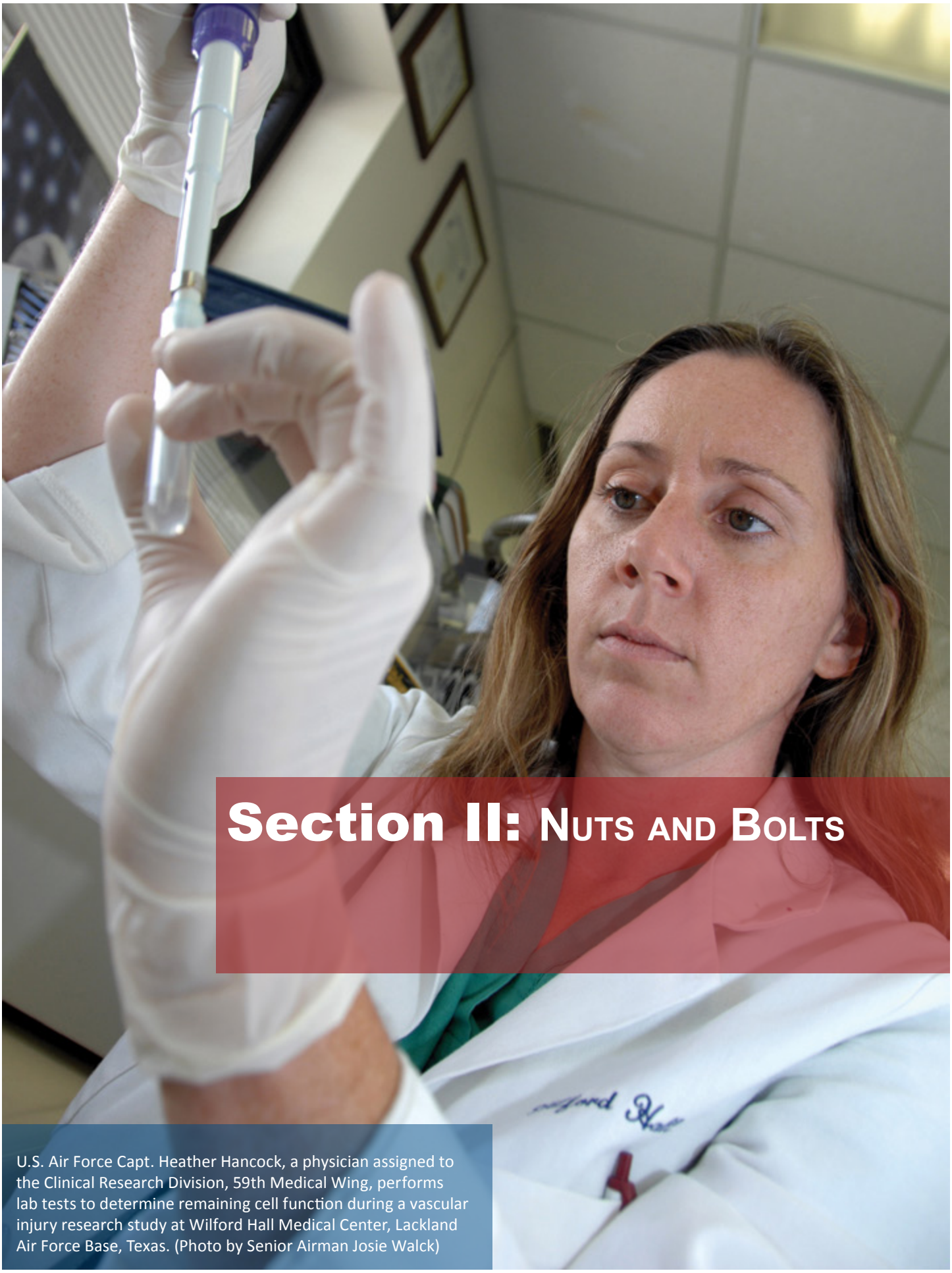


Section II: Nuts and Bolts

U.S. Air Force Capt. Heather Hancock, a physician assigned to the Clinical Research Division, 59th Medical Wing, performs lab tests to determine remaining cell function during a vascular injury research study at Wilford Hall Medical Center, Lackland Air Force Base, Texas. (Photo by Senior Airman Josie Walck)

1. Guide to Research Infrastructure

a. VA Research Infrastructure

VA Office of Research and Development (ORD)

VA ORD is comprised of four services under the direction of the Chief Research and Development Officer (CRADO), who reports through the Deputy Under Secretary for Health for Policy and Services to the Under Secretary for Health. The VA ORD research program is an intramural program spanning the continuum from basic biomedical research through translation of research into practice, emphasizing the health concerns of Veterans. Descriptions of each VA research service and its associated centers of excellence and laboratories are found on the VA websites listed in Figure 2.

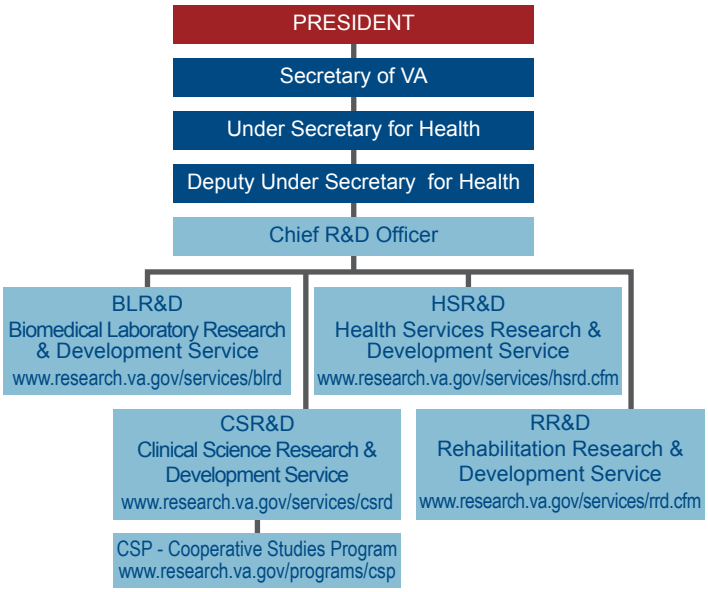


Figure 2. Organization of VA-Managed R&D Administration

Local VA Research and Development (R&D) Services

There are 109 VA medical facilities with active Federalwide Assurances as of July 1, 2013, that are authorized and approved to conduct human subjects research. Research projects approved as VA research may include work conducted at or in VA facilities, including Vet Centers and VA-owned community-based outpatient clinics (CBOCs), and non-VA locations, such as affiliated academic institutions and local communities. The medical center director is responsible for the research program at the facility with oversight by the facility R&D Committee. The associate chief of staff for research (ACOS/R) or research and development coordinator is responsible for the day-to-day management of the research program, while the administrative officer for research (AO/R) is responsible for administrative functions. Staffing levels and local R&D procedures differ across medical centers, so it is important to get a clear picture of local policies, procedures, and timelines when initiating a new research project. The R&D service will be invaluable in helping you navigate the VA system. You can search for research leadership for local VAMCs in the National ACOS/R&D and AO Directory[5] available online.

VA-Affiliated Nonprofit Corporations (NPCs)

VA-affiliated NPCs, also known as Veterans' Research and Education Foundations, are authorized by Congress under 38 USC 7361-7366[6] as flexible funding mechanisms for the conduct of VA-approved research and education. However, VA NPCs are not agents or instrumentalities of VA. Beyond administering research projects and educational activities, the NPCs support a variety of VA research infrastructure and administrative expenses. For example, they typically may provide seed and bridge funding for investigators, fund recruitment of clinician researchers, pay for research administrative and compliance personnel, and support staff and training for IRBs.

VA policy and guidance governing the VA NPCs can be found in Veterans Health Administration (VHA) Handbook 1200.17[7]. In fiscal 2012, as in the previous year, revenue from non-VA governmental research and education sources comprised the largest component of funding received by NPCs. NPCs continue to obtain funding from diverse sources including private sector companies, charitable foundations, private individuals, state and local governments, universities, and federal entities such as NIH, DoD, and the Centers for Disease Control and Prevention.

VAMCs throughout the country have long recognized the benefit of establishing NPCs to help support the conduct of VA-approved research and education. There are presently 84 NPCs, 83 of which are active or becoming active, located in 42 states, the District of Columbia, and Puerto Rico. More information, including a list of NPCs, is available at the VHA Nonprofit Program Office web site[8]. A map showing the location of VA NPCs can be found in Appendix C.

5. www.research.va.gov/about/national_directory.cfm
6. codes.lp.findlaw.com/uscode/38/V/73/IV/7361
7. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2351
8. www.research.va.gov/programs/nppo

b. DoD Research Infrastructure

DoD is governed by the Secretary of Defense, with separate branches for the departments of the Army, Navy, Air Force, and National Capital Region Medical Directorate (NCRMD). Each department has its own research infrastructure, as outlined in Figures 3-5. DoD healthcare research efforts targeting the injured Service member occur primarily within the military treatment facilities (MTFs) and regional medical centers (RMCs). Additional studies are conducted in diverse settings, including research laboratories, military and non-military academic institutions, military bases, and non-military hospitals, including VA facilities.

Army R&D

Within Army Medical Command (MEDCOM) facilities, research is conducted at MTFs and U.S. Army Medical Research and Materiel Command (USAMRMC) laboratories. A region map and list of Army MTFs is found in Appendix D. MTF-conducted clinical research supports graduate medical education (GME) and other allied health programs (e.g., audiology, occupational/physical therapy, nursing). Figure 3 shows the organization of Army-managed R&D infrastructure.

The USAMRMC, a subordinate command of MEDCOM, manages the federally appropriated Army core (President's budget) and assigned Army and Defense Health Program (DHP) Congressional Special Interest (CSI) funding for medical R&D. The CSI appropriations are not part of the President's budget request; they are added to the DoD budget by Congress. The majority of USAMRMC CSI appropriations are executed through one of the following offices or commands within the USAMRMC: Congressionally Directed Medical Research Programs[9] (CDMRP); Telemedicine and Advanced Technology Research

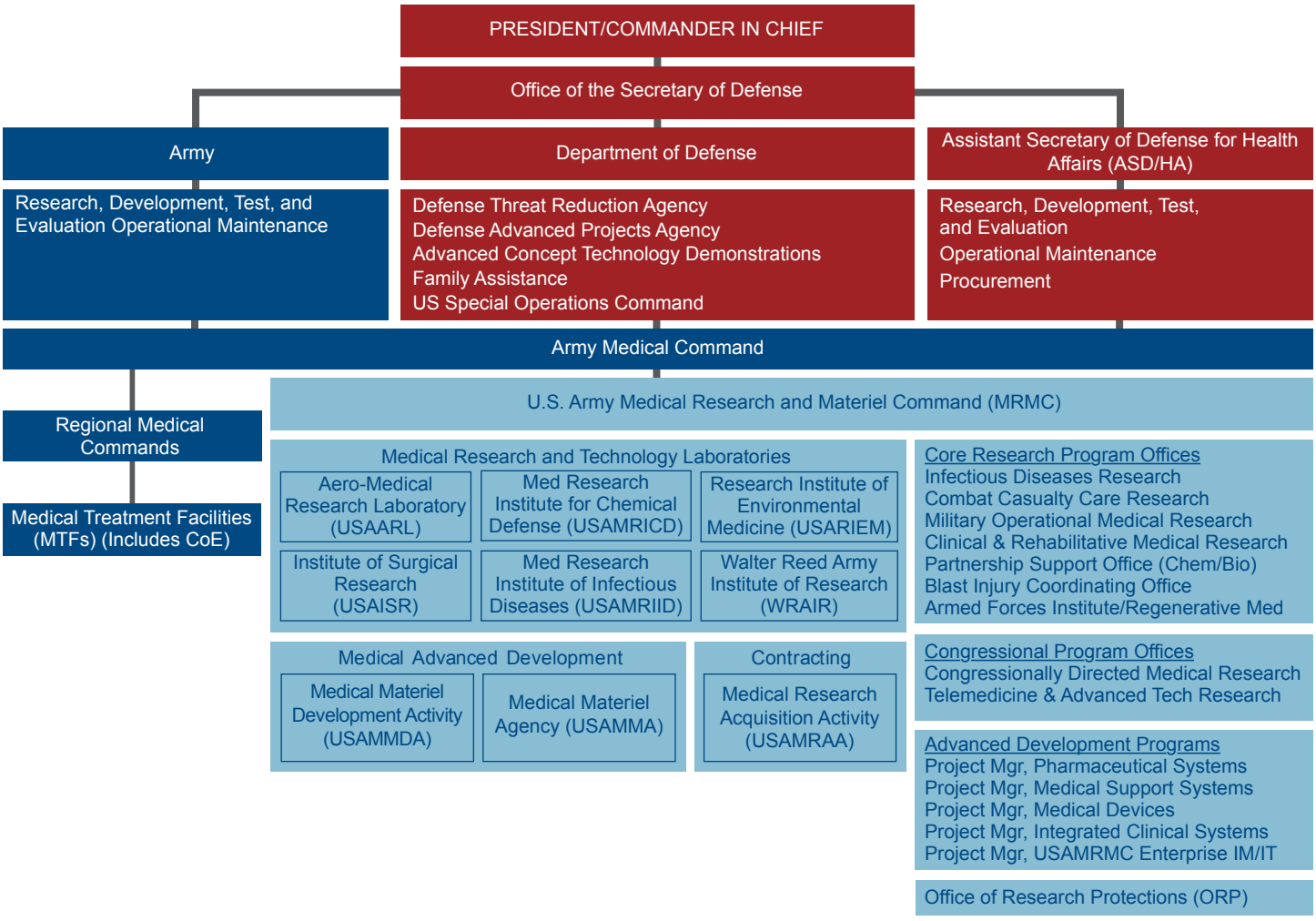
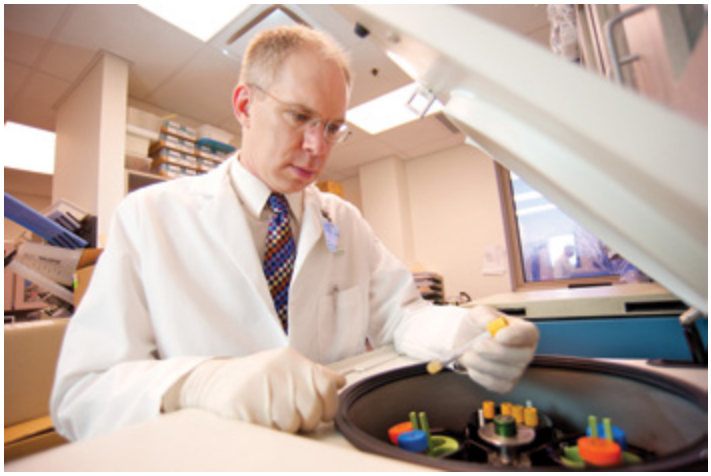


Figure 3. Organization of Army-Managed R&D Administration

9. cdmrp.army.mil

Center[10] (TATRC); U.S. Army Medical Materiel Development Activity[11] (USAMMDA); or U.S. Army Medical Materiel Agency[12] (USAMMA).

Research, development, testing, and evaluation (RDT&E) dollars support both intramural and extramural research. Intramural research encompasses research efforts at MTFs, USAMRMC laboratories, or other DoD laboratories and may include funding for collaborative projects. Extramural research is awarded through program announcements or requests for proposals,



David Canaday, MD, with the Geriatric Research, Education and Clinical Center at the Cleveland VA, studies human immunity to infectious diseases. (Photo by Jason Miller)

which are advertised on Grants.gov and Federal Business Opportunities[13], respectively. Extramural performers include government agencies external to DoD, academia, and industry.

USAMRMC manages and executes research in six basic areas: military infectious diseases, combat casualty care, military operational medicine, chemical biological defense, clinical and rehabilitative medicine, and medical training and health information sciences. Each research focus area is requirements driven. Both intramural and extramural funded research efforts focus on providing solutions (knowledge or materiel) to prioritized capability gaps. Information on the goals and objectives of the six focus area can be found on the USAMRMC website[14]. USAMRMC component laboratories and research institutes and their missions are:

- U.S. Army Aeromedical Research Laboratory[15] (USAARL) research programs solve medical and health-related problems that compromise the safety or deter the mission performance of the aviator and Soldier. The laboratory conducts research on neuro-sensory injury, return-to-duty standards for wounded warriors, and equipment for the medical evacuation environment.
- U.S. Army Institute of Surgical Research[16] (USAISR) provides combat casualty care medical solutions and products for injured soldiers, from self-aid through definitive care across the full spectrum of military operations; state-of-the-art trauma, burn, and critical care to Department of Defense beneficiaries around the world and civilians in our trauma region; and Burn Special Medical Augmentation Response Teams.
- U.S. Army Dental & Trauma Research Detachment[17] (USADTRD) focuses on improving dental treatment and operational readiness, reducing dental emergency rates for deployed Soldiers, and preventing head and neck trauma
- U.S. Army Medical Research Institute of Chemical Defense[18] (USAMRICD) discovers and develops medical countermeasures to chemical warfare agents for U.S. military and U.S. citizens; trains and educates personnel in the medical management of chemical casualties; and provides subject matter expertise in developing Defense and national policy and managing crises.

Subordinate Laboratories

- U.S. Army Center for Environmental Health Research[19] (USACEHR) plans, directs, and conducts research, development, testing and validation for occupational and environmental health surveillance and environmental health technology in support of Force Health Protection.
- U.S. Army Medical Research Institute of Infectious Diseases[20] (USAMRIID) is the lead medical research laboratory for the U.S. Biological Defense Research Program. The Institute plays a key role as the only laboratory in DoD equipped to safely study highly hazardous infectious agents requiring maximum containment at biosafety level 4.

10. www.tatrc.org
11. www.usammda.army.mil
12. www.usamma.amedd.army.mil
13. www.fbo.gov
14. mrmc.amedd.army.mil
15. www.usaarl.army.mil
16. www.usaisr.amedd.army.mil
17. www.usaisr.amedd.army.mil/dental_trauma_research.html
18. usamricd.apgea.army.mil
19. usacehr.amedd.army.mil
20. www.usamriid.army.mil

- U.S. Army Research Institute of Environmental Medicine[21] (USARIEM) conducts biomedical research to improve and sustain warfighter health and performance under all conditions.
- Walter Reed Army Institute of Research[22] (WRAIR) focuses on research for Soldiers in military operations and environments that include stresses and exposures troops encounter and the performance requirements of a deployed military force.

Special Foreign Activities

- Armed Forces Research Institute of Medical Sciences[23] (AFRIMS) defines the epidemiology of military-relevant diseases endemic to tropical regions, observes disease, and develops and evaluates medical products for militarily important infectious diseases.
- U.S. Army Research Unit - Kenya[24] (USAMRU-K) develops and tests improved means for predicting, detecting, preventing, and treating infectious disease threats to military and civilians in East Africa.
- U.S. Army Research Unit - Europe[25] (USAMRU-E) gathers psychological and biomedical data with deployed units to determine the nature and extent of stressors on Soldiers, with the goal of ascertaining the health and performance consequences of these stressors and identifying mediating factors that increase resiliency or vulnerability to stress.
- U.S. Army Medical Materiel Agency[26] (USAMMA) plans, synchronizes, and provides medical logistics for health service support to forces conducting joint and full-spectrum operations.

U.S. Navy Hospital Corpsman 2nd Class Mercedes Blackshear looks at a blood smear in a lab at Camp Lemonnier, Djibouti. (Photo by Chief Mass Communication Specialist Robert P. Gallagher)

Navy R&D

Navy sponsorship of medical research is divided between Science and Technology (S&T) and Advanced Development. The Office of Naval Research (ONR) coordinates, executes, and promotes the S&T programs of the Navy and Marine Corps. ONR is the Navy authority for S&T research funded by Budget Activity (BA) 1 through BA 3. The majority of medical research is managed within ONR's Warfighter Performance Department (Code 34)[27] under the direction of the Force Health Protection[28] Future Naval Capabilities[29] program. The Bureau of Medicine and Surgery (BUMED) is a primary sponsor of medical research performed at higher Budget Activities (BA 5). Additionally, some medical research is conducted within the Navy Systems Commands (SYSCOMs) under sponsorship of the Assistant Secretary of the Navy and Marine Corps for Research Development and Acquisition. These efforts are primarily focused on systems integration and are tied closely to larger acquisition programs. Smaller focused efforts exist, to a limited extent, within other organizations, such as the Naval Postgraduate School and the Naval War College.

The Navy Surgeon General is responsible to the Chief of Naval Operations as OPNAV N093 and also serves as the Chief, BUMED. The Surgeon General has human and animal use responsibility for all medical research conducted within and using Navy and Marine Corps resources, and that is sponsored by the Navy. BUMED M2 (Research and Development) and the Naval Medical Research and Development Command (NMRDC), Frederick, MD, are the policy and oversight organizations for research and research- and analysis-related activities accomplished within or sponsored by the Navy Medicine enterprise.

BUMED Clinical Investigation Program (CIP) is managed through the NMRDC. The CIP, as a component of BUMED, is conducted under authority and direction of DoDI 6000.08[30], with oversight directly responsible to the Chief, BUMED. This function supports basic biomedical science and clinical investigation projects that collect, organize, evaluate, or interpret data collected from DoD health care beneficiaries, laboratory animals, or in vitro tests to study the maintenance of human health.

The NMRDC provides research analysis for issues and projects as assigned and promotes interdisciplinary research so the Navy Medicine mission evolves into a global healthcare community. NMRDC leadership provides guidance for Operational Medicine, Infectious

21. www.usariem.army.mil
22. wrair-www.army.mil
23. www.afrims.org
24. www.usamrukenya.org
25. usamru-e.amedd.army.mil
26. www.usamma.amedd.army.mil
27. www.onr.navy.mil/Science-Technology/Departments/Code-34.aspx
28. www.onr.navy.mil/Science-Technology/Departments/Code-34/All-Programs/warfighter-protection-applications-342/Force-Health-Protection.aspx
29. www.onr.navy.mil/en/Science-Technology/Directorates/Transition/Future-Naval-Capabilities-FNC.aspx
30. www.dtic.mil/whs/directives/corres/pdf/600008p.pdf

Diseases, Biodefense, the DoD Bone Marrow Registry, regulatory compliance, and opportunities development benefiting Navy and Marine Corps Force Health Protection and Readiness. The NMRDC ensures that research and research-related activities are aligned with healthcare delivery, such that Navy health and medical needs are met. The NMRDC further ensures that Navy Medicine's advancements benefit the public trust in domestic and international healthcare, humanitarian assistance, and disaster relief. Figure 4 shows the organization of Navy-managed R&D infrastructure.

Oversight and guidance of research within the Navy's research enterprise is performed through NMRDC working directly with the Naval Medical Research Center headquarters element for work performed in the eight Navy Medicine R&D laboratories:

- Naval Medical Research Center[31] (NMRC), Silver Spring, MD, is the lead laboratory, with the following scientific directorates: Operational and Undersea Medicine, Infectious Diseases, Biodefense, and the DoD Bone Marrow Registry.
- Naval Health Research Center[32] (NHRC), San Diego, CA, performs medical modeling and simulation, and conducts research in epidemiology, human performance, and respiratory diseases.
- Naval Medical Research Unit-2[33] (NAMRU-2) Phnom Penh, Cambodia, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Unit-3[34] (NAMRU-3), Cairo, Egypt, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Unit-6 Detachment[35] (NAMRU-6), Lima, Peru, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Unit - San Antonio[36] (NAMRU-SA), San Antonio, TX, conducts dental research, directed energy effects, and combat casualty care research.
- Naval Medical Research Unit - Dayton[37] (NAMRU-D), Dayton, OH, is the environmental health effects laboratory.
- Naval Submarine Medical Research Laboratory[38] (NSMRL) Groton, CT, conducts health and performance research related to submarine, diving, and surface conditions.
- While not a research laboratory, the Navy and Marine Corps Public Health Center[39] provides epidemiologic data, which may be of interest to collaborators.

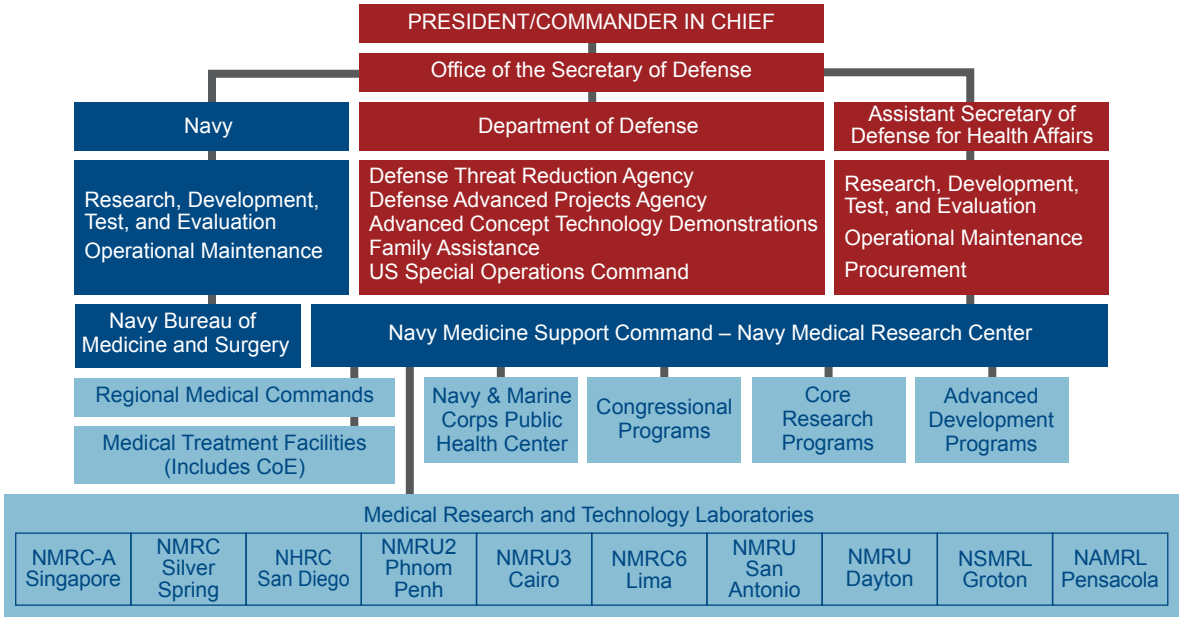


Figure 4: Organization of Navy-Managed R&D Administration

31. www.med.navy.mil/sites/nmrc
32. www.med.navy.mil/sites/nhrc
33. www.med.navy.mil/sites/namru2pacific
34. www.med.navy.mil/sites/namru3
35. www.med.navy.mil/sites/NAMRU6/Pages/namru6.htm
36. www.med.navy.mil/sites/nmrc/Pages/namrusa.htm
37. www.med.navy.mil/sites/nmrc/Pages/namrud.htm
38. www.med.navy.mil/sites/nsmrl
39. www.med.navy.mil/sites/nmcphc

The medical research laboratories are predominantly operated as reimbursable organizations, with a highly competitive staff of world-class researchers and a worldwide presence. The investigators engage extensively in collaborative efforts with academic, public sector, and commercial entities, as well as with other government organizations, through a wide variety of agreements.

Research within the Navy MTFs is administered out of the Navy Medicine Regional Commands: Navy Medicine West and Navy Medicine East. See the region map and medical center list in Appendix E.

- Naval Medical Center, San Diego[40], is the MTF laboratory providing administrative and IRB support to the MTFs within Navy Medicine West: Naval Hospital (NH) Camp Pendleton, NH Bremerton, NH 29 Palms, NH Lemoore, NH Guam, NH Okinawa, and NH Yokosuka. The Navy Center for Combat and Operational Stress Control (NCCOSC) is located on the campus of Navy Medical Center, San Diego.
- Naval Medical Center, Portsmouth[41], is the MTF Laboratory that provides administrative and IRB support to the MTFs within Navy Medicine East: NH Great Lakes, NH Camp LeJeune, NH Jacksonville, NH Pensacola, NH Rota, and NH Naples.

Air Force Medical Research and Development

The Air Force Medical Support Agency (AFMSA) Directorate for Research and Acquisition (AFMSA/SG5) oversees Air Force medical research funding. For those with a DoD common access card (CAC), more information may be found at kx.afms.mil/sg5. Please note that all Knowledge Exchange (kx) websites require either DoD CAC access or sponsorship from the AFMSA Research and Acquisitions Division. To request sponsorship, send an e-mail to SG5Iworkflow@pentagon.af.mil.

The Air Force uses the 59th Medical Wing and the 711th Human Performance Wing for execution of most research funding. These sites include:

- 59th Medical Wing Chief Scientist's Office (59 MDW/ST) Joint Base[42] San Antonio-Lackland, TX
- 711th Human Performance Wing, Wright-Patterson Air Force Base[43] (WPAFB), OH
- USAFSAM Center for the Sustainment of Trauma & Readiness Skills[44] - Baltimore
- USAFSAM Center for the Sustainment of Trauma & Readiness Skills[45] – Cincinnati
- USAFSAM Center for the Sustainment of Trauma & Readiness Skills[46] – St Louis

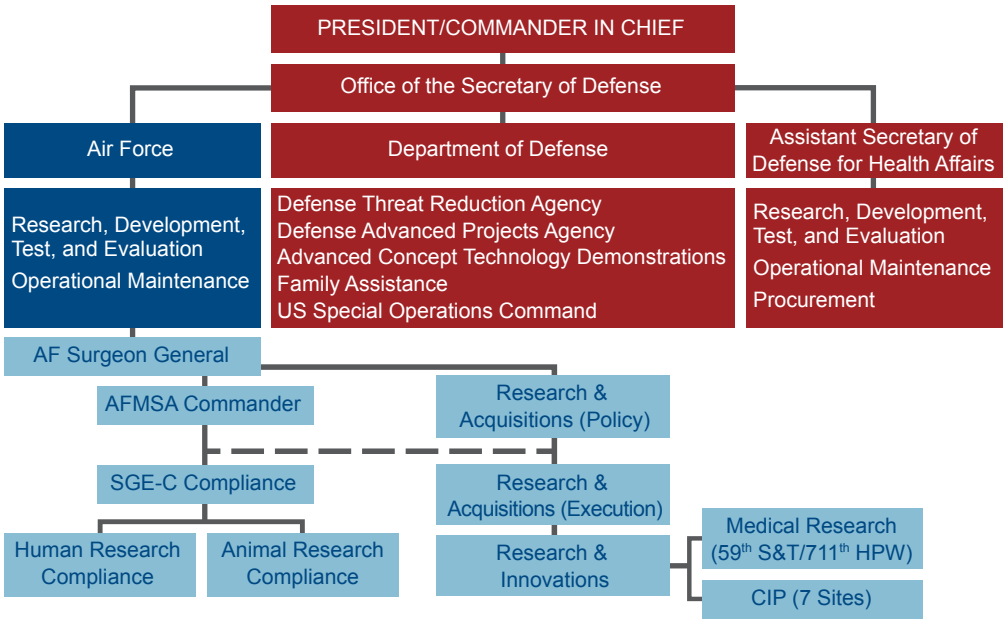


Figure 5. Organization of Air Force-Managed R&D Administration

40. www.med.navy.mil/sites/nmcsd
41. www.med.navy.mil/sites/NMCP2
42. www.whasc.af.mil
43. www.wpafb.af.mil/afrl/711HPW
44. medschool.umaryland.edu/trauma/CSTARS.asp
45. universityhospital.uchealth.com/about/c-stars
46. www.afmmast.mil/Sim Centers/CSTARS-St Louis

Air Force Clinical Investigation Program

In accordance with DoDI 6000.08[47], Funding and Administration of Clinical Investigation Programs, December 3, 2007, the Air Force established seven CIP sites as a means to provide medical education and training for health science programs that include graduate medical education. For those with DoD CAC access, more information may be found at kx.afms.mil/clinicalinvestigations. Many of these sites also provide compliance, equipment, and personnel support for the AFMS medical research program.

The AFMS CIPs include:

- 60th Medical Group, David Grant Medical Center[48], Travis Air Force Base, CA
- 81st Medical Group, Keesler Medical Center[49], Keesler Air Force Base, MI
- 59th Clinical Research Division[50], Lackland Air Force Base, TX
- 88th Medical Group[51], Wright-Patterson Medical Center, WPAFB, OH
- 99th Medical Group[52], Mike O'Callaghan Federal Medical Center, Nellis AFB, NV
- U.S. Air Force School of Aerospace Medicine[53] (USAFSAM), WPAFB, OH
- U.S. Air Force Academy Life Science Research Center[54], Colorado Springs, CO

Defense Health Agency (DHA) National Capital Region Medical Directorate (NCRMD)

The Joint Task Force National Capitol Region Medical (JTF CapMed) was established in 2007 to oversee the implementation of the Base Realignment and Closure (BRAC) 2005 legislation for the National Capital Region (NCR), and to oversee an integrated medical delivery system post-BRAC. On October 1, 2013, the JTF CapMed was disestablished and the National Capitol Region Medical Directorate (NCRMD) established to continue the mission. Medical organizations that conduct research under NCRMD include the Walter Reed National Military Medical Center[55] (WRNMMC), Bethesda, MD; Fort Belvoir Community Hospital[56] (FBCH), Ft. Belvoir, VA; and the Joint Pathology Center[57], Silver Spring, MD.

NCRMD will be organizationally aligned as a directorate within the newly established Defense Health Agency (DHA), which is under the oversight of the Office of the Under Secretary of Defense (Personnel & Readiness) (OUSD/P&R). The Department of Research Programs (DRP) within the WRNMMC supports investigators at the WRNMMC, FBCH, and Joint Pathology Center in the development of research ideas, research collaborations and agreements, and the WRNMMC IRB. Approximately 33 percent of biomedical research protocols approved for execution at all DoD Military Treatment Facilities are conducted within the NCRMD.

47. www.dtic.mil/whs/directives/corres/pdf/600008p.pdf
48. www.travis.af.mil/units/dgmc
49. www.keesler.af.mil/units/81stmedicalgroup.asp
50. www.whasc.af.mil
51. www.wpafb.af.mil/units/wpmc
52. www.nellis.af.mil/units/nellismedicalcenter
53. www.wpafb.af.mil/afrl/711hpw/usafsam.asp
54. www.usafa.edu/df/dfe/dfer/centers/lsrc
55. www.wrnmmc.capmed.mil
56. www.fbch.capmed.mil
57. www.jpc.capmed.mil

2. Where to Start?

You have a great idea for a research project that involves investigators and subjects at both VA and DoD. How can you transform your idea into a viable project? This section provides guidance on finding and securing a collaborator and creating and submitting a research proposal. See Appendix F for a VA/DoD collaboration checklist for investigators.

a. Seeking a Collaborator

The first, critical step in any collaborative research project is to find an interested colleague within the other department, someone with complimentary research interests whom you like and trust and who can devote the necessary time to the project. This person needs to work with you through the planning and implementation stages and champion the project at their agency to ensure proper "buy in" and approvals. Without the right collaborator, your project may never get off the ground.

Research collaboration takes many forms. It can occur between two junior investigators, between a junior and senior, or between two senior investigators. Collaborations may also occur between multiple investigators (or teams) in both departments. Because collaborative research projects take time to produce results, serving as a principal investigator (PI) for such a project may limit research career advancement in the short term. There are instances where junior-level clinicians who have an interest in research but who are not on a research investigator career trajectory would wish to serve as a site PI. It is likely that collaborations between junior investigators will need mentorship from a senior investigator with experience in multisite or interdepartmental collaboration.

Tip

Use your professional networks to identify an experienced, knowledgeable, well-connected, and trustworthy collaborator who has the time to devote to project activities.

Finding a collaborator can be a challenge, especially when you target a new research area. One of the best places to identify potential collaborators is at scientific meetings and conferences. These events present opportunities to meet and discuss shared interests and ideas for potential collaboration. Another good way to identify potential collaborators is to serve as a grant reviewer for other departments or agencies. This provides a way to network with other reviewers, as well as be informed about current proposed initiatives.

Tip

Experienced investigators warn that it is inadvisable for an inexperienced assistant professor or junior investigator seeking an independent research career to be involved in collaborative projects as PI, due to the complexity and length of time involved.
Junior investigators are advised to avoid having their next academic promotion hinge upon the success or failure of a VA/DoD research collaboration.

No current central location provides a complete listing of VA and DoD investigators and their interests and experience. You will need to reach out to researchers and clinicians through phone calls, emails, and networking. Start by contacting investigators from your department who have VA/DoD collaboration experience and ask for their assistance or advice. Contact the chief of research at local VA or military facilities to identify potential collaborators. Find out who in the other agency has done recent research in the area (see Section I.3 of this guidebook) and who has expertise in your field of interest. Additional suggested resources are listed below.

- To identify potential VA research collaborators, contact the VA Health Services Research and Development Service (HSR&D) and speak to one of the program officers in your area. HSR&D maintains a list of active studies and projects[58] in certain topic areas and the responsible scientific program manager (SPM) whom you can consult for additional advice. A periodically updated HSR&D researcher directory[59] that can be searched by name or area of research interest may also be useful to both DoD and VA investigators.
- To identify Army research collaborators, contact program officers at the Telemedicine & Advanced Technology Research Center[60] (TATRC) or

58. www.hsrd.research.va.gov/research/portfolio.cfm
59. www.hsrd.research.va.gov/for_researchers/directory
60. www.tatrc.org

MRMC Research Area Directorates[61] (RADs). Program officers are generally aware of research interests and who has funded proposals. The MRMC homepage[62] is also a helpful resource.

- With respect to identifying Navy collaborators, the NMRDC has policy and oversight responsibility for all Navy medical research and is located within the Navy Medicine Institute at BUMED in Falls Church, VA. The command director or one of the deputies can align researchers with similar areas of interest to laboratories or investigators within the Navy enterprise.
- To identify Air Force research collaborators, contact the AFMSA Directorate for Research and Acquisition, Research and Innovations Division, AFMSA/SG5I, at (703) 681-6112 and ask to speak with the Thrust Area Manager (TAM) for the area encompassing your research, or access the AFMS Knowledge Exchanges (kx.afms.mil) and search the AFMSA/SG5I site. The TAMs in AFMSA/SG5I may be able to direct your protocol towards Air Force interests as well as field collaboration. The Air Force Medical Service Office of Research and Technology Applications (AFMS ORTA), AFMSA/SG5M South, (210) 395-9849, can also assist in finding an Air Force collaborator in coordination with the AFMS research site and is the agency to contact for interagency technology transfer agreements.
- To identify collaborators related to a specific field of study, see the listing for DoD and VA centers of excellence in Table 4.

Tip

When planning your research, develop a back-up plan for possibilities like collaborator reassignment or deployment.

b. Planning Your Proposal

Once you have identified a potential collaborator, you will need to develop a solid plan that spans the entire project duration. Phone meetings are crucial for preplanning, but experienced collaborators recommend that you meet in person with your proposed collaborator and members of their research infrastructure to cement the new collaborative relationship and ensure that all necessary personnel are on board to provide early input. These in-person meetings can be coordinated with other planned travel (e.g., conference attendance).

There are many topics to be considered in developing a plan for collaborative research, including funding source, human subjects participation, scientific methodology, development of sharing agreements or contracts, data sharing, final data disposition, staffing, and budget. Every research project is different, so it is important that you identify the unique, necessary components of your proposed study and then develop action items and a realistic timeline of deliverables that your team agrees upon.

Tip

An experienced VA researcher suggests having a POC at the highest level in the chain of command as possible at each collaborating military site. Start your briefings with your POC early and make sure that all higher-level commanders are included at the briefings.

It is best that PIs do not delegate this type of relationship building to others, but take part in this process. This will help ensure the development of trusted relationships and strong lines of communication.

In some instances, it is useful for new collaborators to jointly publish a paper using existing pilot data or prepare a literature review to develop trust and an understanding of their new colleagues' work style. It also demonstrates that the collaboration is effective and that the proposed work is viable. Small foundation or pilot grants, sometimes available through VA or DoD mechanisms, can be helpful for funding pilot work.

c. Crafting and Submitting a Research Proposal

Developing an innovative proposal and a viable collaborative research plan takes significant time and effort. Investigators must prepare for this time commitment and plan accordingly. The start-up process (from inception of an idea to submission of a proposal) can take from six months to two years, depending on the size and type of the project. Researchers with successful VA/DoD research collaborations confirm that the planning process took much longer than expected.

61. mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.overview

62. mrmc.amedd.army.mil

Optimally, investigators will have administrative and research support staff to assist them in this process. It is unusual for investigators to have funding to support the planning stages of a project; however, planning grants are sometimes available through various agencies, services, and institutions, and it is worth exploring this possibility with scientific program managers, project officers, and leadership. Most successful investigators participating in collaborative projects are situated within departments, facilities, or centers with infrastructure funds to support their planning efforts.

Grants.gov is the official website for information on federal grants, including those awarded by VA and DoD. The website allows you to identify grant opportunities, apply for funding and track your submission's status. Grants.gov is designed to help you search for grant opportunities throughout the federal government. You can search grant opportunities online and in real time or receive email alerts detailing new grant postings.

Department of Veterans Affairs

In VA, research is intramural, meaning only VA employees can conduct research under VA's sponsorship (see VHA Handbook 1200.15[63] for eligibility criteria). All project PIs must be registered with NIH's eRA Commons systems to apply for VA funding. VA proposal submission due dates for ORD services are explained in the submission calendar[64] on the VA Intranet. Some ORD services require that a letter of intent (LOI) be approved before investigators can submit a proposal. Other services require the LOI to plan for reviewer assignment. Additional information regarding the application and submission process for ORD-funded research, including contact information for ORD Central Office staff, is available online at the VA ORD funding page[65].

Department of Defense

The Defense Medical Research and Development Program (DMRDP) is part of the DHP. Focusing on advancing the state of medical science in areas of the most pressing needs, the DMRDP contributes to DoD's overall investment for medical R&D with RDT&E dollars.[iii] A DoD core research program that is included in the President's budget submission to Congress, the DMRDP currently emphasizes work to address posttraumatic stress disorder (PTSD), traumatic brain injury (TBI), limb loss, eye injuries and vision loss, and other conditions directly relevant to battlefield injuries, as well as other ailments that affect both Service members and their families.[iv]

Each of the six major research program areas within the DMRDP (Medical Training and Health Information Services, Military Infectious Diseases, Military Operational Medicine, Combat Casualty Care, Radiation Health Effects, and Clinical and Rehabilitative Medicine) is managed by a Joint Program Committee (JPC), which consists of DoD and non-DoD medical and military technical experts. These experts work through a coordinated effort to translate guidance to best serve research and development needs. They support DMRDP execution functions such as programmatic review of proposals and funding recommendations.[v] The Defense Health Program funding line with a list of JPCs and contacts phone numbers can be found in Appendix G.

The USAMRMC provides program management support to the DHP for the DMRDP. The DMRDP processes are outlined in Figure 6. Additional information can be found online at the DMRDP website[66]. The website for U.S. Army Medical Research Acquisition Activity[67] (USAMRAA), which is MRMC's contracting element, has links to the Broad Agency Announcements (BAAs), Program Announcements, and Requests for Proposals (RFP). There are numerous execution agents responsible for allocating or administering funding or performing research for DoD. These include USAMRMC, USUHS, ONR, AFOSR, BUMED, AFSG, and academia, industry, and government.

DoD's Congressionally Directed Medical Research Program (CDMRP) allows investigators to register online[68] and be notified of all CDMRP-managed program announcements. Most CDMRP submissions require an LOI or preproposal (averaging three pages in length, plus some required administrative information) to be approved prior to proposal submission. Typically, only a select number of investigators submitting LOIs are invited to submit a full proposal.

Navy research funding opportunities are available from a variety of sources. The Office of Naval Research (ONR) provides both extramural and intramural R&D funding at the basic discovery through initial development stages. The Wounded, Ill, and Injured (WII) Program provides funding to both intramural and extramural investigators (with an intramural collaborator) in the

63. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2925
64. www.research.va.gov/funding/process/submission-calendar.cfm
65. www.research.va.gov/funding
66. dmrdp.dhhq.health.mil
67. www.usamraa.army.mil
68. cdmrp.org/Register

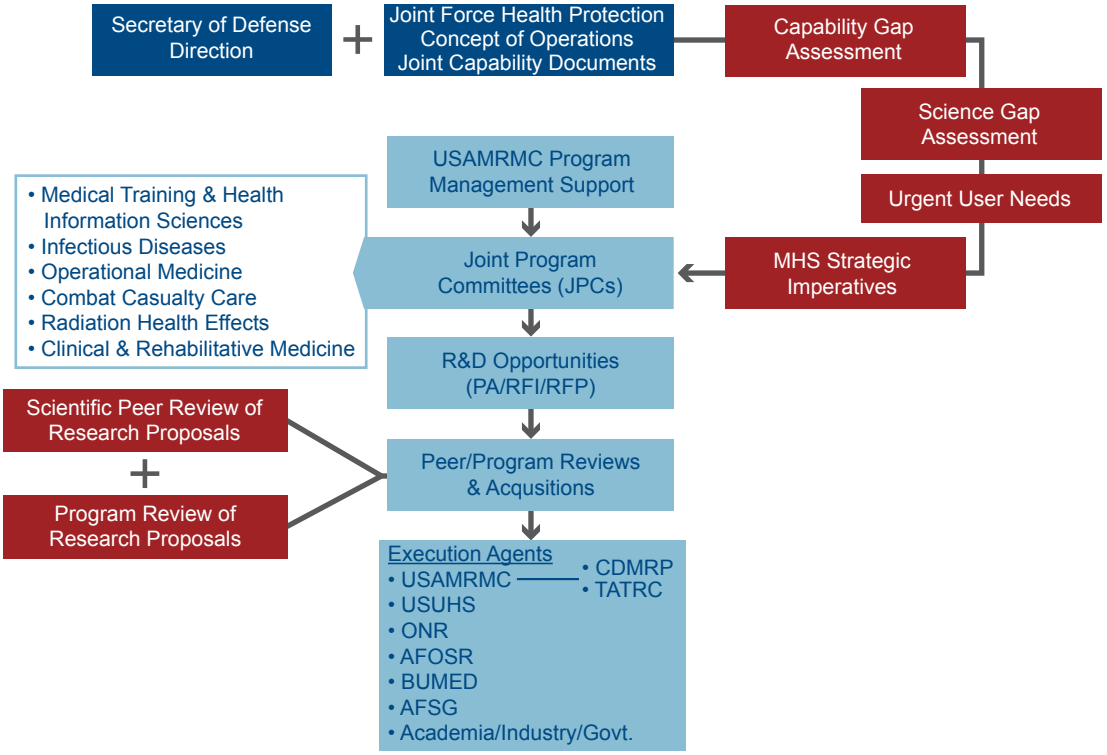


Figure 6: Defense Medical Research and Development Program Process Overview

areas of quality of care, performance enhancement, transition of care, and screening and surveillance. The Clinical Investigations Program (CIP) provides funding to intramural investigators at MTFs; however, extramural collaborations are encouraged. While some human subject research projects may be funded, clinical trials are not supported through this office. Navy announcements and application procedures can be found at the following website: www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx. A short preproposal is generally required for these programs. A call for proposals is distributed annually, with awards announced in October of each year. Proposals can be submitted throughout the year via a regional intramural investigator.

Air Force intramural and extramural research funding opportunities are announced on the Air Force R&D website, kx.afms.mil, available to those with DoD CAC access, and more information may be obtained from AFMSA/SG5I. Extramural awards are accomplished through an annual BAA announcement that may be found at Grants.gov. All DoD extramural research announcements appear on one of two extramural sites for academia and industry: Federal Business Opportunities[69] or Grants.gov.

Additional DoD funding sources can be found in Table 5.

d. Research Integrity

Integrity and trust are fundamental to all aspects of research, from idea generation and proposal writing to peer review, conduct of the study, and dissemination of the results. Trust is essential and may become an issue in collaborative research when sharing intellectual property (IP), particularly in the proposal development and review stages. When a grant is submitted to an agency, the information contained within the grant is considered confidential by the project officer, staff, and reviewers scoring the proposals. This applies to VA and DoD.

Confidentiality statements are signed by reviewers specifically to protect the IP of other scientists. No data are to be copied, transmitted, or used in any other research. Appropriating IP from a submitted proposal may constitute research misconduct. Research misconduct includes fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Under 18 USC Sec 1905, government employees are prohibited from disclosing company proprietary information, under threat of criminal penalty. For the information to be

69. www.fbo.gov

protected by the statute, the proprietary information must be marked as proprietary and must qualify as such. Because of this statute, there is no reason for a federal government employee to sign a commercial non-disclosure agreement. Not only is the company provided automatic protection against the possibility of a government employee disclosing its proprietary information, but, unlike the consequences of any violation of a commercial non-disclosure agreement, there are penal consequences associated with the violation of a criminal statute. Research misconduct is a serious offense that may bar an investigator from obtaining future funds. VHA has published VHA Handbook 1058.02[70] to address this issue.

For the Army, the Department of Health and Human Service (DHHS) Office of Research Integrity guidebook, Introduction to the Responsible Conduct of Research[71] is available to all investigators. The Office of Research Protections offers a regular education series through Defense Connect Online[72]. These public recordings, located under the title "CIP Education Series," cover a variety of human subject protection topics in research. VA researchers can register and watch these trainings. All Navy investigators and collaborators are required to complete human subject protections training as directed by the Department of the Navy Human Research Protection Program (DoN HRPP). Each individual Navy MTF and laboratory receives education in research integrity. Similarly, the Air Force requires human subjects protections training completion certificates for all investigators listed on a human research protocol.

3. Administration of Research Funds

Administration of research funding for collaborative projects requires specialized knowledge and expertise, as policies vary by site and funding (e.g., VA, DoD, NIH, foundation). The basic cost principles (allowable, allocable, and reasonable) apply to the administration of all research funds. The departments as well as the facilities within each department may have differing policies on the use of research funds for personnel, supplies, travel, and equipment. Investigators are advised to consult the research administrators at proposed sites to identify the specific local policies that may impact their project, and work closely with the appropriate administrators to develop a feasible plan.

a. VA Research Funding

Congressionally appropriated VA R&D funds are allocated by VHA Central Office to support research programs and projects at parent and local facilities. All VA funding is intramural. This means that only VA investigators are funded and able to serve as PIs of ORD-funded studies (see VHA Handbook 1200.15[73] for eligibility criteria). Investigators from outside agencies and academic institutions can serve as co-investigators or consultants.

Research awards are funded through a variety of peer-reviewed mechanisms, including but not limited to the following types (listed by name and VA nomenclature):

- Investigator-initiated research (IIR), also called Merit Review Awards (I01)
- Research Career Development Award
  - Career Development Award – CDA-1 (IK_1)
  - Career Development Award – CDA-2 (IK_2)
  - Nursing Research Initiative – NRI (IK_3)
  - Research Career Scientist Award – RCS (IK_6)
- Large-scale, multisite clinical trials (Cooperative Studies Program)
- Quality Enhancement Research Initiative (QUERI)
- Program Project Award (IP_1)
- Centers of Excellence Award (CoEs/I_{50})
- Service-directed projects (SDR)
- Pilot Project/Small Project Award (I_{21})

Research performed in VA is supported by a variety of sources: VA ORD, medical care appropriations, funding

70. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2830
71. ori.hhs.gov/education/products/RCRintro
72. www.dco.dod.mil
73. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2925

from other federal agencies, nonprofit corporations (NPCs), and industry. Local VA research administration is responsible for the administration of VA intramural funds. Research funds from non-VA sources may be administered through a VA NPC, when an NPC exists to support the VA facility.

b. DoD Research Funding

DoD has both intramural and extramural funding mechanisms. Research projects may be funded through a variety of peer-reviewed mechanisms, including but not limited to the following:

- Advanced Technology Award
- Concept Award
- Idea Award
- Career Development Award
- Clinical Trial Award
- Consortium Award
- Translational New Investigator Award
- Investigator Initiated Research Award
- Qualitative Research Award

Subburaman Mohan, PhD (right), and research associate Bouchra Edderkaoui, PhD, of the Loma Linda VA examine osteoclast cells as part of their study on a gene that appears to regulate bone density.

A summary of key DoD research funding opportunities and sources, the type of awards offered, and a synopsis of who may serve as PI for each type of award is shown in Table 5. When a study is conducted at a DoD site, active-duty military, civil service employees (i.e., General Schedule [GS]), and individuals on Intergovernmental Personnel Act (IPA) assignments—all representatives of the government—can serve as PI or site PI. VA investigators, contractors, student interns, and fellows cannot serve as PIs for intramural DoD studies but may act as associate investigators or as research support under the direction of the DoD PI.

DoD funds intramural research efforts through programmed dollars administered by the U.S. Army MRMC, the U.S. Navy (ONR and BUMED), and AFMSA Directorate for Research and Acquisition, Research and Innovations Division, AFMSA/SG5I. Additional efforts, both intra- and extramural, are managed by the MRMC through Congressional Special Interests (CDMRP and TATRC) and allocations through the DHP.

Research Area Directorates(RADs) within the U.S. Army MRMC (Military Infectious Disease Research Program, Combat Casualty Care Research Program, Military Operational Medical Research Program, and Medical Chemical & Biological Defense) and the ONR Code 34 Warfighter Protection Program concurrently manage a large extramural research program with numerous contracts, grants, and cooperative research and development agreements (CRADAs) to provide additional science and technology capabilities from leading academic, private industry, and other government organizations.

Army clinical research efforts are supported at MTFs through graduate medical education (GME) programs supported by operations and maintenance (O&M) medical care appropriations. The projects are overseen and approved by the Department of Clinical Investigations (DCI) at first the local level and next through second-tier review at the MRMC Office of Research Protections.

Navy medical research efforts within MTFs are administered at the regional medical center department of clinical investigations and approved at the local command. Any project may be funded with O&M clinical dollars, RTD&E funds, or extramural resources via CRADAs (see Section II.4.d for more on collaborative agreements). Similarly, Navy medical R&D laboratories may fund a project from any of these sources.

Air Force medical research efforts within the MTFs are also supported through the GME program and can be supported through RDT&E, O&M, or CRADA funding.

c. Research Personnel

It is important to know how research personnel salaries are funded for both agencies. Salary support for VA researchers is outlined in Table 6 and for DoD researchers in Table 7.

VA Research Personnel

Most physician-researchers within VA are similar to DoD clinician-researchers in that their salaries are paid by clinical care dollars and may not be paid by research funds. However, VA physicians, nurses, pharmacists, and other clinicians can and do participate in research activities, with the approval of their supervisors. VA encourages all professionals within its medical facilities

Table 5. DoD Research Funding Opportunities and Sources

SOURCE OF SUPPORT	TYPE OF AWARD	TYPE OF FUNDS	WHO CAN SERVE AS PI?
Intramural/Extramural			
Congressionally Directed Medical Research Program (CDMRP) **cdmrp.army.mil**	Intramural and extramural	RDT&E	Military, industry, academia in defined program areas
Office of Naval Research (ONR) **www.onr.navy.mil**	Intramural and extramural	RDT&E	Military, industry, academia in defined program areas
Intramural			
Telemedicine and Advanced Technologies Research Center **www.tatrc.org**	AMEDD Advanced Medical Technology Initiative funding	O&M	Military or General Schedule (GS) investigators at MTF
Defense Medical Research & Development Program (DMRDP) **dmrdp.amedd.army.mil**	Intramural	RDT&E	Military investigators
Navy Clinical Investigations awards **www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx**	Bureau of Medicine & Surgery (BuMed) intramural funding	O&M	Navy researchers at any Navy MTF (collaborations permitted)
Wounded, Ill & Injured Program (WII) **www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx**	BuMed intramural funding	O&M	Military investigators (collaborators permitted)
Air Force Clinical Investigation Program **www.wpafb.af.mil/library/factsheets/factsheet.asp?id=8981**	Intramural funding	O&M	Military investigators
Air Force Intramural Research **www.wpafb.af.mil/library/factsheets/factsheet.asp?id=8981**	Research management working group	RDT&E	Air Force researchers in DoD facilities working on established Air Force thrust areas
Extramural			
Broad Agency Announcement (BAA) **www.grants.gov**	Contracting action	RDT&E	Industry, academia, federal agencies
Program Announcements **www.grants.gov**	Contracting action	RDT&E	Industry, academia, federal agencies
Requests for Proposals (RFP) **www.fbo.gov**	Contracting action	RDT&E	Industry, academia, federal agencies
Tri-Service Nursing Research Program (TSNRP) **www.usuhs.mil/tsnrp/GrantApplications/callforproposals.php**	Awards to nonprofit organizations, public university	O&M	Military nurses – active duty, Reserve, National Guard, and retired military registered nurses (eligibility criteria vary by type of award)
Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Programs DOD: **www.acq.osd.mil/osbp** AF: **www.afsbirsttr.com/Portal.aspx** Navy: **www.navysbir.com www.onr.navy.mil/en/Science-Technology/Directorates/Transition/SBIR-STTR.aspx**	Contracting action	RDT&E	Industry and academia in defined program areas
Defense Advanced Research Projects Agency (DARPA) **www.darpa.mil**	Contracting action	RDT&E	Industry, academia
Miscellaneous Announcements **www.fbo.gov**	Contracting action	RDT&E, O&M	Industry, academia

to participate in research. VA also employs research scientists who are funded by research funds to conduct specific projects; career development awardees; and career scientists whose salaries are supported by research dollars for specific time periods. Some VA researchers also have appointments with their affiliated academic institution which may provide the researchers some salary support as well as academic title and tenure in connection with their outside activities at the university. VA mandates that only VA employees may engage in research in VA facilities, and VA researchers will therefore all have VA appointments, which may be paid, unpaid, full or part-time, or under the IPA Act. VA appoints affiliated university and non-profit corporation staff as without compensation (WOC) employees, under express statutory authority in Title 38, and such appointees are federal employees of the department for the duration of their appointments and subject to all applicable federal laws and regulations. Among those requiring WOC appointments at VA are fellows, residents, students, volunteers, and visiting scientists who are not compensated by VA for their research-related duties, and others who are not compensated VA employees, including, at times, DoD collaborators.

Table 6.
VA Research Personnel and Funding Sources

POSITION	SOURCE OF SALARY SUPPORT
VA Research	
Physician Researcher	Clinical care dollars only
Career Scientist and Research Scientist	Research efforts paid by research funds
Academic Researcher	Research or institutional funds
Research Coordinator/ Assistant	Research funds
Clinician (Non-physician) Researcher	Clinical care dollars or research dollars

DoD Research Personnel

DoD funding for research is either by Service line (Army, Navy, Air Force), which are DoD RDT&E appropriated funds, or through the Defense Health Program (DHP). DHP is a single appropriation consisting of operation and maintenance; research, development, test, and evaluation; and procurement funds designed to finance the non-military personnel requirements of the Military Health System (MHS). DHP research funding under the DHP RDT&E portfolio supports both intramural and extramural medical research activities.

Tip

It is important to choose a centralized project coordinator or director with VA/DoD collaborative or multisite study experience, and to plan for on-site study coordinators who have experience conducting research at each study site.

The DHP RDT&E appropriation also funds research programs for medical information management/ information technology, medical research to reduce capability gaps, support to continental United States and outside of continental United States medical laboratory facilities, and the Armed Forces Radiological Research Institute. Funds are available for obligation for the period of two fiscal years. O&M funds in the DHP appropriation support the delivery of health care in MTFs and private sector and associated operating activities, education, base operating support, and management oversight, including infrastructure management of clinical investigations. Funds are available for obligation for the period of one fiscal year.

There are restrictions associated with these funding sources. For example, DoD employees are full-time paid federal employees, and therefore, typically their salaries may not be supplemented from a research grant. Military Service members perform research activities as approved by their local chain of command. Civil service employees and contractors conduct research activities as outlined in their position description and the project's statement of work (SOW). Contract staff funded with science and technology dollars perform research activities within the MTFs or research laboratories but cannot provide clinical care unless privileged by the facility to do so, or under the clinical privileges of an assigned provider. Fellows and interns can provide research assistance appropriate to their educational program and allowed by their GME program training director. DoD researchers may have scientific academic affiliations with the Uniformed Services University of the Health Sciences (USU/USUHS)[vi].

DoD research centers may have researchers who are salaried, tenured through the USU or on "soft money" (grant-funded, usually supported by foundations). They may also have external research personnel through CRADAs.

Table 7. DoD Research Personnel and Funding Sources

DoD RESEARCH POSITIONS	MILITARY PERSONNEL	CIVILIAN PERSONNEL		CRADA
	Active Duty Military	Research Dollars Line-funded Military Services & DHP RDT&E	Clinical Dollars Line-funded Military Services & DHP O&M	Academic/Private Sector and NFP research institutions
Clinician Involved in Research				
Clinician in Military Treatment Facilities (MTFs)	X		X	
Clinician in Department of Clinical Investigations	X	X (Navy)	X	
Clinician in research laboratories	X	X (AFMS)	X (Navy)	
Contract staff		X (Navy)	X	X
Dedicated Research Staff				
Personnel in research laboratories	X	X	X (Navy, AFMS)	X
Contractor/Intergovernmental Personnel Act (IPA)		X	X (Navy)	X
Academic Affiliation				
Faculty position at military institution (USUHS, service academies, etc.)	X		X	
Student/intern/fellow in military education program	X		X	
Faculty/student in civilian academic institution	X (Navy, AFMS)	X		X

d. Budget Preparation

Preparation of the proposal budget has implications for later funding administration. Thus, it is important for investigators to understand funding mechanisms and make informed choices in their proposal development. Work with an experienced grants administrator on appropriate budgeting for personnel and other expenses, so adequate funds are requested for the project.

Personnel

There are a variety of options for staffing a research study (see Figure 7). Administratively, it is simplest if there are already experienced staff at the proposed site who can be dedicated to your project. Unfortunately, this is often not the case, and new staff members need to be recruited. Staffing within VA and DoD presents challenges. Researchers have found it very difficult to directly transfer funds between VA and the military. Investigators are advised to work closely with an experienced research administrator at each site to assist in the recruitment and staffing process. Each PI needs to decide whether or not new personnel staffing will be completed at the lead PI's (coordinating) site or through the local sites, where data collection is occurring. Clearly, this decision impacts the allocation of research funds to participating sites.

The following mechanisms, also shown in Figure 7, may be available to secure research support personnel:

- VA hire (USAJOBS): Research staff and investigators with scientific, investigatory, or technical expertise may be hired under the Title 38 Medical Support Authority or Schedule B. These excepted and time-limited appointments are considered "term" and last for a specified duration, with the possibility of

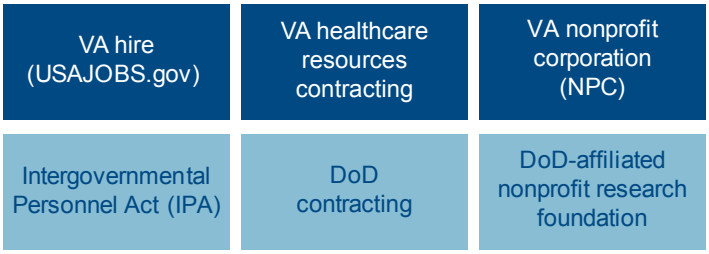


Figure 7. Mechanisms for Staffing a Study

renewals. Schedule B hiring authority can be used for individuals at a GS 11 or higher for individuals working on a part-time or intermittent basis. Title 38 MSA can be used for any GS level. There is a VA-wide cap of 800 appointments under Schedule B. Individuals who work in an administrative capacity in research may not be hired under these authorities. Many other research positions are continuing in nature and may be filled by competitive procedures with a career-conditional or career appointment; temporary or term appointment; or other noncompetitive hiring authority for which the individual is eligible, such as Veterans Recruitment Authority, Schedule A (213.3102(r)), or 30% Veterans SCD (5 USC 3112). These options should be used whenever appropriate. For more details about term employees, visit USAJOBS[74] and see your local HR specialist for additional information. Please note that it can take many months for you to get your staff on board due to the complexities of the federal hiring process.

Tip

Both VA and DoD facilities require varying levels of security clearance, credentialing, appointments (e.g., VA WOC), and information security access requirements. Check with each proposed study site and make sure that all study staff receive the appropriate approvals and access. This process can be lengthy and can hold up study activities if not done in advance.

- VA healthcare resources contracting: In some instances it may be appropriate to contract for the required services in accordance with the Federal Acquisition Regulations (FAR). PIs will need to discuss options with their administrative officers and local contracting departments. The time from initiation to signing of a contract can be weeks to months, depending on the workload at your local VA and the amount and complexity of the contract. See Section II.3.e for more contracting information. It is usually preferable for personnel to be hired as employees rather than acquiring services through a VA contract.

Tip

Due to increasing travel restrictions, it may be difficult to coordinate meetings with coinvestigators at conferences. PIs should be sure to itemize the travel requirements related to the performance of the research study in their applications, budgets, and protocols.

- VA NPC: If the project is funded through a non-VA source, you may staff either on a contract or hire employees through a VA-affiliated nonprofit corporation. NPC staff must obtain a VA WOC appointment. Staffing through NPCs may be more expedient than most of the other options, as they are unburdened by federal hiring regulations. Full-time employees of the NPC may be eligible for full benefits packages through the NPC.
- DoD contracting: DoD facilities may use contract labor to staff a research study. These contracts typically pay for work done on an hourly basis and may or may not include benefits such as healthcare, vacation, or sick time. The time from initiation to signing of a contract can be weeks to months, depending on the complexity of the contract and the mechanism used. Some contracts may be precompeted for various labor categories (e.g., "indefinite delivery, indefinite quantity" contracts) with a vendor to provide labor on an "as required" basis. These contracts often are the most efficient way to obtain labor to support a particular project but they often have higher fees than other types of contracts.
- Nonprofit foundation: Not all DoD medical facilities are able to administer research funds directly; thus, they usually work with one or more affiliated nonprofit organizations (NPO) to procure research personnel and supplies. If you are a VA investigator

74. help.usajobs.gov/index.php/Temporary_and_Term

with VA funding and an active collaborator with a DoD investigator, you may initiate a contract with an affiliated NPO that can hire staff, provide them with a full benefits package, and place them at a DoD research site (after appropriate clearance by the DoD institution).

- Academic institution: DoD investigators often partner collaboratively with academic investigators with special research knowledge and skills. Working with the DoD partner to achieve appropriate DoD site clearances, an academic institution can hire contract personnel support or place university personnel on-site at a DoD facility to facilitate the research endeavor.
- Intergovernmental Personnel Act (IPA): Another alternative for funding research personnel is the IPA. IPA appointments are intended to facilitate federal-state-local cooperation through intermittent, part-time, or full-time arrangements for up to two years. Assignments may be extended for an additional two years. The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the federal government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations. These are typically used for higher-level personnel who are career or career-conditional federal employees being used in another agency for inherently governmental actions. They are not used for contract employees. An IPA assignment may also be used when a research assistant is working at an affiliated university and can be assigned to work on a project at VA or DoD. IPA assignments must be implemented through an agreement clearly defining relevant factors of the assignment. For details about the IPA Mobility Program, see the U.S. Office of Personnel Management[75] Web page.

At the Minneapolis VA, Scott Sponheim, PhD (at computer), inspects EEG recordings of brain waves from OEF/OIF Veteran Andrew Lisdahl as lab assistant Peter Lynn monitors electrode placement. (Photo by April Eilers)

There are a number of regulations surrounding the correct use of VA IPA assignments. A nonfederal employee may be assigned under an IPA agreement to a federal agency either by appointment or detail. If by appointment, the nonfederal employee is deemed an employee of the federal agency for all purposes except enrollment in a federal retirement system, Federal Employees Group Life Insurance (FEGLI), or the Federal Employees' Health Benefits (FEHB) (unless the appointment results in loss of coverage under a group health plan in which the premium is paid by the nonfederal organization). Those assigned by detail remain employees of their permanent organization for most purposes. For example, they are not eligible to enroll in FEHB programs, FEGLI, or any retirement system for federal employees. Assignees who have served for four continuous years may not be sent on another IPA assignment without at least a twelve-month return to duty. Successive assignments without a break of at least 60 calendar days are regarded as continuous. For those with Talent Management System (TMS) access, VA's Nonprofit Program Office (NPPO) offers a training resource[76] for completing an IPA between VA and a VA NPC.

- Other options: DoD facilities may have additional options for government contracting, such as the Oak Ridge Institute for Science and Education (ORISE) fellowships[77].

Travel

Most projects include funding for travel expenses for necessary preplanning visits, study site visits during the project, data analysis, manuscript preparation, and post-study collaborator meetings. VA limits the inclusion of travel in research budgets. Funding for foreign travel may not be requested as part of a VA-ORD research application budget. Check with local administrators to confirm their policies. You will need to speak with your local VA research administrator and travel officer to follow local travel policies. If you are a researcher working with other sites, decide if money for travel will be coordinated at your site (if VA) or allocated to the participating sites (e.g., other VAs) or to a DoD site through an affiliated nonprofit organization to allow payment for travel at the local level. DOD employees use the Defense Travel System[78] for

75. www.opm.gov/policy-data-oversight/hiring-authorities/intergovernment-personnel-act
76. www.research.va.gov/programs/nppo/training.cfm
77. see.orau.org
78. www.defensetravel.osd.mil/dts/site/index.jsp

travel arrangements. Because DoD employees may have restrictions on how their travel is procured, you will need to develop a plan for travel coverage with the site researcher.

Supplies/Equipment

As the study PI, you will need to determine what supplies and equipment you, your collaborator, and your respective agencies can provide and what needs to be purchased with project funds. As with travel, decide whether supply funds are allocated to participating sites (e.g., other VAs), or to a DoD site through an affiliated nonprofit organization. Some grants allow split disbursements to each participating institution. The particular sponsor or program officer will be able to provide this information. Alternatively, if you are a VA investigator, all purchases can be made through your VA site and shipped to participating sites. All equipment purchased with VA funds belongs to the purchasing VA. This means that it needs to be accounted for in the yearly inventory or EIL (Equipment Inventory Listing) if it meets certain criteria. In VA, equipment is defined as an item of property that has an acquisition cost of $5,000 or more and an expected service life of more than one year. In addition, if tagged equipment is shipped to other study sites, a VA Government Property Loan Form (VA Form 0887) or DOD 1149 Requisition and Invoice/Shipping Document must be completed and filed. Read the funding instructions carefully, as there may be restrictions on certain items (e.g., capital equipment).

Additionally, there are added rules and regulations for VA regarding sensitive items (e.g., computers, CD drives, cell phones etc.) regardless of cost.[viii] The PI should be aware of department-specific rules related to processing, storage, and transmission of department-owned sensitive information on IT equipment purchased or owned by the collaborating department. A written agreement between the departments outlining relevant security controls may be required in such instances. See Section II.4.d for details. VA investigators should talk with their local research office and chief information officer (CIO) to discuss issues involving sensitive information to be transmitted or stored on non-VA equipment.

Consultants

You may acquire consultant services by contract for your project using proper acquisition procedures in accordance with FAR. If the qualified consultant is identified in your proposal, it may be possible to execute a contract to acquire the consultant's services. If you are not allowing for full and open competition and wish to contract with a specific consultant, you will need to draft a sole source justification and approval document. These types of consultant contracts are subject to limitations on rate of pay and length of time. According to the SF424 (R&R) Application Guide for VA-ORD, annual costs for consultant services may not exceed $2,500 per consultant.

Subject Stipends

If you want to pay your subjects for their study participation, speak with the IRB Coordinator at each potential study site, as many facilities have IRB policies specific to subject compensation. If your subjects are active duty military, they are permitted to receive compensation only under very limited circumstances (e.g., blood draw). There may be exceptions related to participation for those who participate in research during civilian or personal time.

Information Technology (IT)

VA does not allow IT expenses to be included in the budgets for most grant submissions. Standard general-purpose IT equipment (e.g., desktop computer, printer, telephone, cell phone) is the responsibility of the medical center at which the research is being performed, and nonstandard IT equipment (e.g., a server, videoconferencing equipment) is the responsibility of the ACOS/R and CIO using IT funds made available specifically to support research. Speak with the local VA administrative officer to determine whether you are able to request IT funds for your project.

DoD follows similar rules and, in the MTFs, uses O&M BAG4 (budget activity group 4) funds for IT.

Miscellaneous

Each facility has individual costs associated with services, which may include an IRB usage fee, CRADA fee, or other administrative costs (e.g., IPAs). Other acceptable fees would be for time on a university- or NPC-owned core instrument.

Ultimately, these budgetary decisions depend on the scope of your project and the policies and procedures of your department or funding agency. To ensure a timely project start, regular and close communication with your research administration and that of your participating sites is necessary. If you are one of the first investigators at your institution to collaborate with DoD or VA, you may be asking your research administration to break new ground to identify new procedures and

solutions for administering funds. It is important to allow extra time (a minimum of six to nine months in advance of project start) to work through these issues. Experienced researchers stress the importance of being "down in the weeds" in early stages of the project, involved with the details and gaining an understanding of the rules and regulations on both sides of the collaboration.

Facilities and Administrative (F&A), General and Administrative (G&A) or Indirect Costs

Indirect costs are costs that are incurred for common or joint objectives and cannot be assigned to a specific grant, contract or project. The costs are for shared services such as libraries, physical plant operation and maintenance, utilities and administrative support. VA-ORD applications may not contain any indirect costs. Most DoD submissions allow for this charge. Documentation to support the indirect cost rate (e.g., the current DHHS Rate Agreement or other policy document) must be provided.

e. Contracting

The contracting office is a very important partner in ensuring successful research contracts. This office needs to be aware of your needs and timeline at an early stage. Contracting officers are warranted officials who are authorized to contract for the government in accordance with FAR. Their expertise is necessary to ensure compliance.

Contracting officers at VA and DoD facilities are responsible for many types of contracts (e.g., clinical products, services, construction), and rarely do they have staff dedicated to research contracting. Therefore, it is important to develop good working relationships with your local contracting officers to help facilitate timely execution of your contracts. Contracting officers are the only individuals legally authorized to enter into a contract and obligate government funds. See Figure 8 for more detail on the steps involved in the contracting process.

General Contracting Advice

If you have identified a source with the required skills to perform the work, you may be able to justify a sole-source contract supported by a Justification and Approval (J&A) document drafted in accordance with FAR. The J&A should demonstrate the unique and innovative concept, or, demonstrate a unique capability of the source to provide the particular research services proposed. The J&A will be published on the Internet at www.fbo.gov (Federal Business Opportunities). Therefore, it is essential that the technical information be accurate.

It is necessary for investigators or their project management staff to write the SOW for each contract for the local contracting officer. Do not give this task to the contracting officer, as he or she does not know the technical details of the requirement. When writing an SOW that involves personnel, carefully specify the qualifications and technical requirements of the services to be procured. Specify the roles and responsibilities of the contractor (e.g., recruitment, consenting subjects, conducting testing, and analyzing data), duty hours, and requirements for timelines, deliverables, communication, and supervisory oversight. You must also provide objective standards for performance (e.g., data quality, data accuracy). List the individual tasks to be performed under the contract. Make sure that all deliverables are specifically spelled out in the SOW.

Figure 8. General Steps in the Federal Acquisition Regulations Contracting Process

Tip

Problems with administration of research funds may arise during the course of the project and are particularly common in the start-up phase. Communicate with your funding sources so they understand the problems you face and any resulting delays. Make sure they know in advance so they can make adjustments as needed.

Requirements should be tailored for each solicitation to consider, in addition to cost, non-cost factors such as past performance, technical excellence, management capability, key personnel qualifications, and prior experience.

Other contracting considerations:

- Option years (or phases), if required, need to be included.
- If the contract covers the storage, generation, transmission, or exchange of sensitive information, ensure that the contract contains the security clauses required by departmental policy (e.g., VA Handbook 6500.6).
- Any service contract will be awarded in accordance with federal law and regulations.
- Develop an Independent Government Cost Estimate prior to soliciting offers to evaluate contractor proposals. Indirect costs and fees vary substantially between contractors. Estimates must be supported by a rational basis.
- Clinicians and contracting staff at treatment facilities may need guidance to understand the technical requirements. If possible, bring on a seasoned researcher as a consultant to your project.
- Follow up with the contracting office on a regular basis to check on the status of your contracts and to get updates, and make sure that it stays on the contracting officer's radar screen.

VA Contracting Considerations

Contracts executed in VA need to take the Procurement Action Lead Time (PALT) Schedule into consideration. The PALT schedule is estimated based on the number of days that it may take to plan, solicit, and award a given action for the purchase of goods or services. Variables that may impact the PALT schedule include: current staffing levels in the contracting office, the skill sets of the acquisition staff, the number of requirements awaiting action, and the size and complexity of the requirement. Day one of the PALT schedule begins when a complete requirement package is received by the contracting office. In VA, an acquisition of less than $25,000 may have an estimated time of 40 days, while a more complicated acquisition may take up to 220 days or longer.

DoD Contracting Considerations

Check with your research administration to ensure that you are able to accept and contract all study funds before you submit your funding proposal. Research funding is very complex to negotiate and difficult to understand; by getting the facts early on, you can save significant frustration and avoid potential disappointment. Work closely with your research administration to ask and answer some important questions, such as:

- What type of money are you receiving: RDT&E or O&M? This determines the type of work that can be performed.

Tip

It is important for researchers to understand how reporting requirements differ across DoD and VA, how funds must be spent, how to address invoicing requirements, whether funds can be carried over from year to year, and whether a no-cost extension can be obtained in the event of unforeseen delays.

- When do funds expire? Some funds can be applied only to service contracts that have a maximum 12- to 24-month lifespan. In some cases, if money is not fully obligated during the fiscal year, it is lost.

If you are a DoD investigator pursuing extramural funds, strongly consider partnering with a colleague from VA or from an affiliated academic institution. You could submit your application for funding, listing that individual as the lead PI. Academic affiliates can often manage and distribute research dollars in a more effective and timely manner than can DoD sites. Funds received at academic institutions, however, can have administrative overhead charges deducted from the award. Working out these details early can avoid

problems during the conduct of the study. In the proposal and all other documents indicate that, as the site PI, you will oversee efforts at your site. If you go this route, you may want to complete a Memorandum of Understanding (MOU), Memorandum of Agreement (MOA), or CRADA with your collaborating PI, clearly outlining roles and responsibilities. Please see detailed information on agreements in Section 4.

Another alternative is to submit the proposal through a DoD-affiliated NPC. Historically, one of the most important roles for DoD-affiliated NPCs is receiving and dispersing funds for research conducted at MTFs. If a DoD investigator submits the research proposal through an affiliated NPC, the NPC is responsible for executing the contract.

4. Formalizing the Collaboration

A critical step in establishing collaboration between VA and DoD investigators is the creation of a formal agreement that defines the relationship and the expectations of the parties involved. There are a variety of mechanisms available to formalize an agreement, including Interagency Agreements, CRADAs and MOAs/MOUs. The types of agencies involved, the requirements of collaborating parties, their relationship, and their goals will define the type and structure of the agreement. Once research is funded, the agreement must address the scope of work as proposed.

Tip

As DoD implements the Defense Health Agency (see Sec. 1.1.b), expect changes in the regulatory requirements across the Services and plan for administrative time to address new requirements.

This section suggests general topic areas that should be considered, discussed, negotiated, and agreed upon prior to embarking on new research collaboration and points to key resources that provide more detailed guidance on creating formal agreements.

It is essential to have a formal agreement that describes the roles, expectations, rights, and responsibilities of research partners in as clear, comprehensive, and uncomplicated a manner as possible. Agreements are a manifestation of relationships, with all of their implicit benefits and challenges, so they can sometimes be difficult to encapsulate within a document with legal terminology and requirements. That said, for an agreement to be legally binding, it must capture the requirements, roles, responsibilities, expectations, deliverables, period of performance, and other pertinent considerations, terms and conditions must be based on an authority. Both departments have resources at the national and local levels to assist investigators in drafting these agreements.

a. VA Resources for Collaborative Agreements

The local VA administrative officer is the first resource to consult about collaborative agreements. Several offices in VA can assist investigators in developing collaborative research agreements. The Office of General Counsel (OGC) will provide advice regarding the form of any needed legal agreement. The Technology Transfer Program (TTP) can help with drafting SOWs and offers a range of other CRADA resources. The mission of TTP is to serve the American people by transferring the results of worthy technologies developed by investigators to the public. Within the federal government, technology transfer more specifically refers to the commercialization of discoveries developed with federal R&D funding for public and private needs. While primary emphasis is placed on transfers to various nonfederal organizations, technology transfer can also occur between federal agencies. VA Tech Transfer has a variety of model agreements available online.

b. DoD Resources for Collaborative Agreements

Military collaborators should typically seek advice regarding collaborative research agreements from their local clinical research office, in consultation with the local chain of command. It may be prudent to seek and consult military legal counsel to ensure the viability of any proposed agreements. There are several resources that may be beneficial to DoD investigators and research administrators.

The USAMRMC Office of Research and Technology Applications (ORTA), otherwise known as the

Technology Transfer Office, coordinates all intellectual property licensing on behalf of all USAMRMC's subordinate laboratories from the federal sector to nonfederal parties. The ORTA office at each subordinate laboratory coordinates CRADAs, Material Transfer Agreements (MTAs), Interagency Agreements (IAAs), Nondisclosure Agreements (NDAs), and other technology transfer transactions. For more information, see technologytransfer.amedd.army.mil.

The Department of Navy (DoN) Technology Transfer (T2) Program[79] is responsible for the sponsorship, management, administration, and execution of domestic T2 activities. Heads of designated Navy laboratories have been delegated authority to enter into CRADAs from the Chief of Naval Research. Each lab has an ORTA manager who can assist in developing and promoting effective partnerships between government and other nonfederal or federal entities. Additional information is available at the ONR Office of Transition[80]. For Navy Medicine, the lead agents are located within the Naval Medical Research Center[81] (NMRC). Each of the regional medical centers and R&D laboratories will its own ORTA as the local POC to initiate these agreements.

For the Air Force, the AFMS ORTA (AFMSA/SG5M South) is the POC for research-related agreements and facilitating collaborative research. Contact the AFMS Technology Transfer Focal Point at (210) 395-9820 or (210) 395-9849. SG5 relies on the 59th Medical Wing (MDW) and the 711th Human Performance Wing (HPW) to conduct research. The 59th MDW/ST provides oversight and support to investigators assigned to the 59th MDW, Joint Base San Antonio – Lackland, TX, the San Antonio Military Medical Center (SAMMC), and affiliated organizations. The Clinical Research Program is requirements driven to address Air Force-unique, Joint, and Coalition scientific needs in en route care-combat casualty care/trauma critical care, clinical and rehabilitative medicine, diagnostics, therapeutics, medical modeling and simulation training, and nursing research aligned to Air Force Medical Service (AFMS) Thrust Areas. Clinical research is conducted at Joint Base San Antonio – Lackland, TX, at the 59th Clinical Research Division, Fort Sam Houston, and other SAMHS sites. Additionally our investigators conduct research with Service collaborators at the Battlefield Health and Trauma Research Institute (e.g., U.S. Army Institute of Surgical Research, Navy Medical Research Unit-San Antonio, and 711th HPW).

c. Content of Agreements

Key areas that should be addressed in any formal agreement are shown in Figure 9.

Resource Sharing	Roles and Responsibilities of Each Party	Research Reporting and Publication
A detailed list of all resources being supplied by the partners must be included in any agreement. Resources include space (facilities and infrastructure), personnel, funds, equipment, and an estimate of in-kind kind providing for the project and how and where they will be utilized.	A list of roles and responsibilities of each party should be specific, and include specific deliverables.	Rules regarding the dissemination and publication of study results and any other special publication considerations should be detailed in the agreement. See Section II.7
Negotiating and Protection of Intellectual Property	**Human Subjects Issues**	**Data Use Issues**
Provisions relating to the ownership disclosure and publishing rights of IP produced during the research, as well as any existing invention, should be addressed in the agreement. IP is created by individuals and groups to further knowledge. Some endeavors may have commercial value, and one or more parties may want to protect the IP they bring to the collaborative effort. Forms of IP protection include patents, copyrights, trademarksand trade secrets. For frequently asked questions about copyright issues affecting the federal government, see: www.cendi.gov/publications/048copyright.html	Human subject concerns should be addressed. See Section II.5	Difficulty in data use issues can delay a project's start or even stop a project in its tracks. It is critical that potential problems be addressed early on so that valuable time is not wasted later in the project. See Section II.6

Figure 9. Key Content Areas for Research Agreements

79. www.onr.navy.mil/Science-Technology/Directorates/Transition/Technology-Transfer-T2.aspx

80. www.onr.navy.mil/Science-Technology/Directorates/Transition/.aspx

81. www.med.navy.mil/sites/nmrc

d. Types of Agreements

Interagency Agreement (IAA)

An interagency agreement is a request for goods or services from another federal agency. It requires many of the same components as a contract, such as a statement of work, available funding, clinical protocol, and a supporting rationale justifying the need for the agreement. The Economy Act, 31 USC 1535[82], and the VA/DoD Healthcare Resources Sharing Authority (38 USC 8111[83], 10 USC 1104[84]) are two specific authorities.

Memorandum of Agreement/Memorandum of Understanding (MOA/MOU)

A memorandum of agreement (MOA) is a document written between parties to cooperatively work together on an agreed-upon project or meet an agreed-upon objective. The purpose of an MOA is to have a written understanding of the agreement between the parties. The MOA can also be a legal document that is binding and that holds the parties responsible to fulfill their commitments, or it can simply be a nonbinding partnership agreement. A memorandum of understanding (MOU) is a nonbinding legal document describing a bilateral agreement between parties. It expresses a convergence of will between the parties, indicating an intended common line of action, rather than a legal commitment. It is a more formal alternative to a "gentleman's agreement," but generally lacks the binding power of a contract. VA has developed a Memorandum of Understanding checklist[85], available online. This checklist may be used for VA/Academic Affiliate IRB arrangements and for VA/VA IRB arrangements. It contains elements that ORD and ORO believe need to be discussed between the parties when MOUs are drafted and should be documented in the MOU.

Cooperative Research and Development Agreement (CRADA)

The CRADA is a legal, enforceable agreement, usually between a federal agency and one or more nonfederal parties (see 15 USC 3710a[86]).

CRADAs are meant to facilitate the transfer of commercially useful technologies developed in collaboration with the nonfederal partner from the federal laboratory to the public. In some limited circumstances, a CRADA can be used between two federal agencies (such as VA and DoD); however, it is generally not an appropriate mechanism for this purpose. In these situations a technology transfer Memorandum of Agreement (T2 MOA) can describe the nonmonetary resources (such as personnel, equipment, and space) and background technologies that will be provided by each party. Refer to Section II.3 of this guidebook for more information on use of research funds for study-related activities.

CRADAs allow a nonfederal entity access to research resources, including personnel, services and property; protect background inventions, trade secrets, and confidential information; establish intellectual property ownership and licensing options in advance of an invention; and leverage federal expertise to develop products with the potential for commercialization.

Tip

Sometimes broad Interagency Agreements exist that may be related to your study or to your study population. If you learn that such an agreement exists, discuss with your project officer to see if it affects you.

CRADAs can be initiated by federal or industry partners. Some address all provisions in very concrete terms, while others allow for flexibility. The CRADA approval process varies in time from a short turnaround to six months or more, depending on the complexity of the research, the availability of a master CRADA, and the negotiation process necessary for proposed revisions to the CRADA. The process typically involves research administrators, the technology transfer offices, and attorneys from each department.

A CRADA (or T2 MOA) typically contains General Provisions (the legal framework) and a statement of work that provides a detailed explanation of the research to be performed, identifiable phases leading to completion of the research project, deliverables, funding requirements, and time estimates for overall project

82. www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleII-chap15-subchapIII-sec1535.pdf
83. www.gpo.gov/fdsys/granule/USCODE-2011-title38/USCODE-2011-title38-partVI-chap81-subchapI-sec8111/content-detail.html
84. www.gpo.gov/fdsys/pkg/USCODE-2012-title10/pdf/USCODE-2012-title10-subtitleA-partII-chap55-sec1104.pdf
85. www.va.gov/ORO/ORO_Checklists.asp
86. www.gpo.gov/fdsys/granule/USCODE-2011-title15/USCODE-2011-title15-chap63-sec3710a/content-detail.html

completion. The CRADA and the associated statement of work will be written to provide a scope of any potential license for any intellectual property developed under the CRADA.

Within DoD, CRADA templates vary across Service branches, laboratories, and MTFs. The Air Force and Navy have their own standard templates. The Army delegates its CRADA preparation to individual labs. The Clinical Investigations Regulatory Office (CIRO) signs the CRADAs for all Army medical centers. The majority of these CRADAs are with the collaborating nonprofit research foundations. Army medical centers have umbrella CRADAs with these foundations, so only an SOW is needed for each protocol. The Navy and Air Force have a clinical trials template for human subject research and a nonclinical trials template for other types of studies. A limited-purpose template is also available for data sharing. The various standard Navy CRADA templates and other cooperative agreements[87] (e.g., MOAs) are available online.

The Air Force Medical Service Office of Research and Technology Applications (AFMS ORTA) is the focal point for clinical research technology transfer. It supports translation of clinical research into practice, facilitating AFMS clinical researchers' collaborations with industry, academia, and local, state, and federal agencies. For more information contact the AFMS ORTA at (210) 395-9820 or (210) 395-9849.

Note that the Navy will use only the Navy template, and the AF will use only the AF template. This means that if your project involves Navy and AF sites, you will want to discuss the possibility of having one site take the lead on the CRADA and the other creating an MOA/MOU between the participating Navy and AF sites. If that is not an option, your project will require both a Navy and AF CRADA with the external collaborators. The Army will typically agree to use the Navy or AF template on a multiparty CRADA. A DoD-wide template is expected to be developed and deployed by the end of 2014.

5. Human Research Protections

Research involving human subjects that is conducted at both VA and DoD institutions must have IRB approval on behalf of all participating sites before any research activities can begin. If this requirement is not managed proactively, it may increase usual project start-up time by six months or more. Researchers may contact VA ORD to discuss this possibility. They should also contact their own institutions' Human Research Protections Office or the Army, Navy, or Air Force headquarters human research protections office early in the process of developing a multisite protocol. Research activities include subject recruitment, data collection, or chart reviews. Because VA and DoD have different rules and regulations governing human subjects research, collaborative research efforts need to comply with both sets of regulations.

The Federal Policy for the Protection of Human Subjects codified in 45 CFR 46[88] is also known as the Common Rule. The Food and Drug Administration (FDA) policy for protection of human subjects is codified in 21 CFR 50[89], with institutional review board requirements described in 21 CFR 56[90]. In addition to following the Common Rule, both VA and DoD have additional policies and procedures regarding human subject protections:

- VA: VA codified the Common Rule as 38 CFR 16[91]. Procedures for the protection of human subjects in VA research are primarily described in VHA Handbook 1200.05[92].
- DoD: The Army, Navy, and Air Force version of the Common Rule is 32 CFR 219[93]. DoD adopted the subparts 45 CFR 46 B, C, and D in their entirety. In addition, DoD research is governed by 10 USC 980[94], DODI 3216.02[95], and 32 CFR 219.
- Service-specific regulations include but are not limited to the following: Navy Human Research Protections Program (DoN HRPP) follows DoN instruction SECNAVINST 3900.39[96] (series); AF HRP follows Air Force Instruction AFI 40-402[97]; and Army HRP

87. www.med.navy.mil/sites/nmrc/Pages/ott_ttf.htm
88. www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
89. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50
90. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=56
91. www.gpo.gov/fdsys/pkg/CFR-2002-title38-vol1/content-detail.html
92. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2531
93. www.tricare.mil/hpae/_docs/32cfr219.pdf
94. www.gpo.gov/fdsys/granule/USCODE-2011-title10/USCODE-2011-title10-subtitleA-partII-chap49-sec980/content-detail.html
95. www.dtic.mil/whs/directives/corres/pdf/321602p.pdf
96. www.fas.org/irp/doddir/navy/secnavinst/3900_39d.pdf
97. www.fas.org/irp/doddir/usaf/afi40-402.pdf

follows Army Regulations AR40-7[98]; AR 70-25[99]; AR 40-38[100].

The IRB approves research studies and reviews ongoing studies to ensure human subjects are protected. Most IRBs have three categories for research review:

- Exempt vs. nonexempt research: Some research involving human subjects or their bodily materials does not require review and approval by the IRB as defined in section 219.101(b) of title 32 CFR. Investigators who believe their human subjects research activity is exempt from review should request an exemption from the IRB.
- Expedited: Expedited reviews may be conducted in certain cases by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB, in accordance with the requirements set forth in 32 CFR 219.110 and 38 CFR 16.110.
- Convened Review: A convened review procedure consists of a review of the protocol at a convened meeting of the IRB.

a. VA Research Oversight

The VA Office of Research Oversight[101] (ORO) advises the VA Under Secretary for Health concerning all matters of research compliance and assurance, including: human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, debarment for research impropriety, and other matters that the Under Secretary for Health may assign. The ORO is also responsible for developing and conducting research compliance officer education programs as directed by the Under Secretary for Health. ORO staff members, including local research compliance officers, conduct frequent routine and "for cause" reviews of VHA research programs to assess compliance with policies and procedures and provide oversight to ensure VA facilities initiate written, appropriate action plans to correct any problems and deficiencies identified by VA and other federal oversight bodies.

The Program for Research Integrity Development & Education[102] (PRIDE) within ORD focuses on protecting participants in VA human research. PRIDE is responsible for policy development and guidance and training and education in human research protection throughout VA.

VA Levels of Review

The human subject research approval process in VA is multi-tiered. After investigators obtain approval from the local IRB and all applicable subcommittees, they then obtain final approval from the local R&D Committee. There are three possible R&D Committee and subcommittee outcomes:

- Approve
- Conditionally approve (require modifications to secure approval)
- Disapprove

All research projects require oversight by a local VA R&D Committee and the appropriate subcommittee, such as the IRB or Subcommittee on Research Safety (SRS). The VA R&D Committee reviews the work and recommendations of the IRB and other subcommittees and must approve the research before it can begin. The authority and responsibilities of the R&D and its subcommittees are detailed in VHA Handbook 1200.1[103].

Tip

Allow sufficient time to obtain approvals. Most IRB, R&D, and other subcommittees meet only once a month, and each facility has internal timelines.

Because the R&D Committee can't approve the protocol until approval has been received by all subcommittees, at best it can take three to six months from the initial submission to the final approval. If any of the committees disapprove the protocol or require substantial changes, the entire process may need to be repeated.

If the study involves more than one site, separate IRB and R&D Committee approvals are needed prior to study initiation at each site. This can substantially increase the project timeline.

b. DoD Research Oversight

Human subjects research protection in DoD is under the auspices of the Assistant Secretary of Defense,

98. www.apd.army.mil/pdffiles/r40_7.pdf
99. www.apd.army.mil/pdffiles/r70_25.pdf
100. www.apd.army.mil/pdffiles/r40_38.pdf
101. www.va.gov/ORO/About_ORO.asp
102. www.research.va.gov/PRIDE/
103. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2038

Research and Engineering. This office oversees all DoD components that either conduct or support human research, each with its own mechanisms in place to ensure implementation of the provisions of DoDI 3216.02[104].

Army Research Oversight

The Army Human Research Protections Office (AHRPO) is located within the Army Surgeon General's Office and is charged with oversight of the issuance of Army Human Research Protections Assurances and of the Human Research Protections Programs at each Army-assured institution.

The Headquarters MRMC Office of Research Protections (ORP) is located at Fort Detrick, MD, and ensures that research that is conducted, contracted, sponsored, supported, or managed by MRMC, and MRMC-supported U.S. Army Medical Command clinical investigations involving human subjects, human anatomical substances, or animals, are conducted in accordance with federal, DoD, Army, MRMC, and international regulatory requirements. In addition, the HQ MRMC ORP:

- provides guidance regarding human subjects protection and animal welfare policies and procedures,
- develops educational activities for persons conducting or managing research, and
- implements an active USAMRMC compliance oversight program.

The ORP has four major subordinate offices: AHRPO, the Clinical Investigations Regulatory Office (CIRO), the Institutional Review Board Office (IRBO), and the Animal Care and Use Review Office (ACURO).

Army Levels of Review

DoDI 3216.02[105] requires that selected categories of DoD-supported or -conducted research receive a component headquarters-level review to determine if all federal, DoD, and local requirements— to include host national regulatory review requirements—have been met. Currently either the AHRPO or MRMC ORP (as delegated) provides these reviews on behalf of the Army. Departments of Clinical Investigation (DCIs) support the IRBs at Army MTFs. See Appendix D for a breakdown of DCI programs by region. The DCIs in the Army are designed and staffed to support the research efforts of the GME programs. Over the past number of years, this role has expanded to support all research efforts within each MTF where a DCI is located.

Certain categories of MTF protocols require preapproval by the headquarters office before they can receive an implementation letter. Those categories include investigational drug studies, investigational device studies, and studies requiring a waiver of 10 USC 980 to conduct research subject to 21 CFR 50.24[106], "Exception from Informed Consent for Emergency Research." A detailed list of categories requiring preapproval can be found in DoDI 3216.02. Studies that are funded by the MRMC must receive approval from the ORP office before funds for the project are used to support human research activities.

Army Protocol Review

All proposals and protocols funded by the MRMC must be reviewed by the MRMC ORP, HRPO. During this review, an assigned Human Subject Protections Scientist (HSPS) identifies the roles and responsibilities of all individuals involved in the research.

The HSPS identifies the individuals, their institutions, and the nature of their involvement in the conduct of the studies. This mapping activity (see sample form in Appendix H) is the first action necessary to identify all institutions involved that meet the definition of engagement in research involving human subjects and thus require a Federal Assurance of Compliance and an IRB review on behalf of the engaged institutions. This initial mapping of responsibilities ensures that the institutions engaged in research involving human subjects meet all DoD regulatory requirements. Those institutions whose involvement constitutes either a "service" or research not involving human subjects (e.g., analyzing coded data without access to the codes) are not required to hold an assurance, and no IRB review is required.

Army MTF Research Approval Timelines

Each MTF has a unique environment, with varying residency and fellowship training programs, and varying research support infrastructures. No two DCIs are staffed in the same manner. Approval times vary based on the complexity and risk level of the protocol and can range from two weeks for a determination of research not involving human subjects (RNIHS), to four to six months for a greater-than-minimal-risk (GTMR) study that requires full board review. Scientific review is

104. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2038
105. www.dtic.mil/whs/directives/corres/pdf/321602p.pdf
106. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24

required in advance of IRB review by the majority of MTFs; others conduct scientific review simultaneously with the IRB review. All protocols undergo an administrative review prior to IRB review. Approval time for projects that require collaboration agreements may be longer. Investigators conducting multisite studies are encouraged to pursue a single IRB review on behalf of the participating institutions. Many Army MTFs regularly rely on other DoD institutions' IRBs.

Navy Research Oversight

Navy research is conducted under the authority of the Navy Surgeon General through the DoN HRPP. The Surgeon General delegates the authority to conduct research to commanders, commanding officers, or officers in charge of Navy MCs and MTFs through the research assurance process.

The DoN HRPP is located within the Navy Surgeon General's Office. It is charged with overseeing compliance with DoD and Navy human subjects protection, which includes all research for which the Navy or Marine Corps provides:

- personnel (including researchers or subjects),
- materiel (including nonpublic information used to identify or contact prospective subjects),
- property or facilities, or
- sponsored funding, regardless of source (intramural or extramural).

DoN HRPP guidance[107] on Navy-sponsored research for Navy Commands and extramural performers is available online.

Navy Levels of Review

All levels of research review and determinations are made by the Navy Clinical Investigation Departments (CIDs), located at the three major Navy medical centers or at the respective Navy R&D laboratory with research administrative support. From RNIHS to FDA-regulated GTMR trials, these IRBs review and recommend approval for all levels of research. Final approval of the research rests with the commanding officer of each respective MTF or R&D laboratory.

The CIDs in the Navy are designed and staffed to support the research efforts of the medical staff. They are also the administrative support for the Navy MTF regional IRBs. The DoN HRPP oversees and provides headquarters-level compliance review for Navy IRBs. Navy research protocols are reviewed by Navy IRBs that, in turn, recommend them to the commanders, commanding officers, or officers in charge. With few exceptions, Navy research is approved at the command level and does not require a higher-level review or approval.

A listing of Navy commands holding research assurances[108] may be found online. Investigators desiring to conduct research at commands without an assurance are encouraged to contact the DoN HRPP, which may assist that command in acquiring IRB support and an assurance. This process is not difficult and can often be completed in parallel with protocol and grant writing.

The Navy has a strong GME program. The largest residency programs are found at the Naval Medical Centers: Naval Medical Center Portsmouth and Naval Medical Center San Diego. These MTFs provide excellent research support and encourage collaborations.

Agreements exist between each of the major medical centers to accept IRB review from one of the other two Navy MTF sites. This exists to expedite the approval of multicenter trials within the Navy. Approval at each site still resides with the respective commanding officers.

Navy Approval Timelines

Each MTF has a unique patient mix and staffing environment. As a result, no two CIDs are similarly organized or staffed. Despite this, approval times are centrally tracked and monitored quarterly for each region. Current approval times from submission of a completed protocol have consistently ranged from three to six months for all levels of complexity at the NMCSD and NMCP. Scientific review procedures vary between commands but must be completed prior to IRB submission. CRADAs or other agreements can be processed in parallel, and IRB approval is not dependent upon their prior completion. However, these other agreements, if necessary, must be completed before the research may begin.

Air Force Research Oversight

DoDI 3216.02[109] requires that selected categories of Air Force-supported and -conducted research receive a component headquarters-level review to determine if all federal, DoD, and local requirements—to include host national regulatory review requirements—have

107. www.med.navy.mil/bumed/humanresearch/resource/Pages/DONHRPPGuidance.aspx#guidance_gen
108. www.med.navy.mil/bumed/humanresearch/resource/AssuranceInformation/Pages/NavyAssurances.aspx
109. www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

been met. AFMSA/SGE-C and their designated human research protection officials (HRPOs) provide these reviews on behalf of the Air Force. IRBs at Clinical Investigation Facilities (CIFs) support the Air Force MTFs. The CIFs in the Air Force are designed and staffed to support the research efforts of the GME programs. Over the past few years, this role has expanded to support all research efforts within each MTF where a CIF is located.

Certain categories of Air Force IRB-approved protocols require preapproval by the headquarters oversight office (AFMSA/SGE-C) before they may begin. These categories include studies of greater-than-minimal risk, investigational drug studies, investigational device studies, and studies requiring a waiver of consent under 10 USC 980 to conduct research subject to 21 CFR 50.24.

Air Force Protocol Review

Before they can begin, all activities supported by the Air Force and conducted by non-DoD institutions that may constitute research involving human subjects must be reviewed by a DoD HRPO in accordance with DoDI 3216.02. The role of the HRPO is to ensure compliance of both the activity (with respect to human research protection requirements, if applicable), and the non-DoD institution's review of the activity (e.g., by their non-DoD IRB).

In addition to consideration of other compliance issues, the HRPO identifies the individuals, their institutions, and the nature of their involvement in the conduct of the studies to identify all institutions whose activities constitute engagement in research involving human subjects and thus require a Federal Assurance of Compliance and an IRB review.

Air Force MTF Research Approval Timelines

Each MTF has a unique environment comprised of varying residency and fellowship training programs. No two CIFs are resourced in the same manner. Approval times vary based on the category, complexity, and risk level of the protocol and can range from weeks to months. Scientific review is required in advance of IRB review by the majority of MTFs; others conduct scientific review simultaneously with the IRB review. All protocols undergo an administrative review prior to IRB review. Approval time for projects that require collaboration agreements may be longer.

DoD Multisite Collaboration Approval

In multisite DoD research, IRBs will often agree to rely, through a signed Institutional Agreement for IRB Review (IAIR), on one IRB for review and oversight. However, investigators at each site will still be responsible for obtaining local command approvals as required per site. Note that VA and DoD generally will not engage in IAIRs with each other due to differing review regulations, so research involving engaged institutions at both VA and DoD sites should plan for a minimum of two IRB reviews: a VA IRB and a DoD IRB, usually selected on the basis of the lead PI's affiliation.

DoD currently does not use a centralized IRB system for multisite research across DoD. Exceptions to this exist in three cases, two of which are focused on a particular field of study:

- The Uniformed Services University of Health Sciences (USUHS) IRB serves as the central IRB for DoD studies related to infectious diseases.
- The USAMRMC IRBO serves as the central IRB for DoD studies related to auditory and vestibular research.
- The USAMRMC IRBO serves as central IRB for research engaging more than one Army site. With appropriate institutional agreements, DoD institutions can rely on one another's IRB.

TIPS *for navigating the VA and DoD IRBs:*

1. It helps to have a research assistant or other staff member who is experienced with the IRB process working for each party in the collaboration.
2. Identify which IRBs must approve your project and plan accordingly. Check with both VA and DoD, as they will have differing requirements.
3. Leave plenty of extra time to prepare the application(s).
4. Have a contact person in place at each IRB.
5. Obtain a "pre-review" of the application in advance of submission to the IRB. If there are any special circumstances, consult with the IRB Chair, if possible.
6. Each committee and institution has its own templates. Templates change frequently. Be in contact with the local IRB office to ensure you are using the correct forms and templates.
7. The IRB approval process for a multisite project is serial and can take 12–18 months. Anticipate how long each step will take and develop an appropriate timeline prior to grant submission, if possible.
8. Ensure that you have letters of support and/or signed impact statements from all departments and services that will be used during the study.
9. Make certain that you have a local site investigator who is trained and qualified at each study site.

6. Data Security and Resources

In most collaborative research projects involving human subjects, there is a need to share data among the research partners. Along with ensuring that all the human subjects protections requirements are met, details about which data elements and how the data are shared and managed must be discussed, written into the protocol, and described in the Health Insurance Portability and Accountability Act (HIPAA) authorization. In some cases, a separate formalized agreement will need to be executed. These agreements depend on the study, the type of data being shared, and the location of data collection and analysis.

One of the most efficient ways to share data across agencies is to keep all data to be shared in a coded, de-identified format with only approved personnel having access to the code key for the combined data set. Each agency could have the code key for its own data. De-identification may not be possible for protocols in which identifiers (e.g., dates of treatment) are necessary to analyze the data.

Data should also be kept in a separate, secure location (either automated or physical) that is accessible only to trained personnel listed on the IRB application. In addition, a common coding format should be established at the beginning of the project. Both agencies implement Health Insurance Portability and Accountability Act (HIPAA) and HIPAA Privacy Rule regulations, so sharing identifiable data is particularly challenging. It is up to PIs, in consultation with their department's privacy officers and information security officers (ISOs), to determine which data are necessary and able to be shared in a coded, de-identified format, and to acquire the approvals to share them. If the data cannot be de-identified for purposes of the protocol, ensure that there is legal authority for the disclosure of the identifiable data, such as valid HIPAA authorization.

VA requires that when data from multiple study protocols are to be combined for analysis, the data must be placed in a combined data set with IRB oversight. A HIPAA authorization signed by subjects must clearly describe this arrangement.

Some clinicians, staff, or collaborators may need to be credentialed and privileged or given a special appointment, depending on the type of data they need to use. Speak with your research administration to determine what needs to be done to make sure your team has the data access it needs.

a. Data Security and Infrastructure

VA Data

In most cases, original research data generated by VA investigators during the conduct of VA-approved research are owned by VA, and their use and storage must meet all federal standards, including, but not limited to: the Federal Information Security Management Act of 2002 (FISMA), National Institute of Standards and Technology (NIST) standards for computer systems and encryption, the Privacy Act of 1974, Title 38 information security statutes, and HIPAA Privacy and Security Rules.

In addition, there are a number of VA and VHA policies with which investigators and research staff must comply, such as VA Handbook 6500[110] and VHA Handbook 1605.1[111]. More information is available online at www.va.gov/ORO/Research_Information_Protection.asp

The Office of Research Oversight (ORO) has developed interim guidance on data disclosures for collaborative research studies. The guidance clarifies current requirements for the disclosure of VA research data to academic affiliates and other non-VA entities for "collaborative" human subject research, including requirements related to the retention of VA research records, disclosure of data under HIPAA, data ownership, information security, "dual appointment" research investigators, and combining data collected at a VA site and an affiliate or collaborator site.

There are many aspects of data and information security that need to be taken into consideration before a new VA research project gets under way. Most of these requirements need to be addressed in a research application and must be met before a protocol receives approval. Each VAMC has an information security officer (ISO) and privacy officer who will review the IRB application for data security and privacy concerns. Additional information and data security considerations include the following:

- Access to VA computer systems is restricted (through virtual private network or VA network ID).

110. www.va.gov/vapubs/viewPublication.asp?Pub_ID=56

111. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1423

- To access VA computer systems, you must be a VA employee (WOCs and IPAs are considered employees for this purpose) or a contractor.
- To have access, you must undergo an appropriate level background investigation, which must be favorably adjudicated.
- Clinical trial monitors (CTMs) can have limited access without requiring a background investigation.
- Use of portable storage devices and DVD/CD burners is restricted (and only VA-approved encrypted devices may be used).
- Everyone using a VA computer must comply with annual VA Information Security Training.
- There are strict requirements for storage of VA data.
- When electronic data are stored outside of a VA computer system (thumb drive or external hard drive), encryption of all individually identifiable health information and other sensitive data is required.

VA Informatics and Computing Infrastructure (VINCI)

The VA Informatics and Computing Infrastructure (VINCI) is a centralized data repository that serves as a common point of entry for approved VA and affiliated investigators with both human subjects and VA Virtual Private Network (VPN) approval. Data available on VINCI include the Corporate Data Warehouse (CDW), Medical SAS Data Sets, DSS NDEs, VSSC, DSS Web Reports, and Vital Status Files. Descriptions of available data can be found on the VA Intranet at vaww.vinci.med.va.gov/vincicentral/Data.html. Through VINCI there are opportunities to coordinate use of multiple data sources using available tools for data processing, analysis, reporting, and natural language processing (extracting information from text).

Following VINCI project approval, VA researchers and their colleagues access VINCI through a secure, virtual working environment using a certified VHA network computer, or through an approved VPN and remote desktop application. The data and the desired applications used to analyze the data are found in this remote computing environment. The data analysis is done directly on VINCI-CDW on servers located at the Austin Information Technology Center. Using this central, secure location ensures that no data are transmitted to local PC hard drives. Researchers can bring their own data sets to VINCI, as long as they have approved Data Use Agreements and/or IRB approvals. DoD researchers working on approved VA/DoD projects can work with their VA colleagues to access the VINCI environment by securing WOC and other needed credentials.

VINCI is a partnership among the VA Office of Information Technology, the VA Office of Informatics and Analytics, and the VHA Office of Research and Development. To ensure the protection of Veterans' data, VINCI maintains compliance with the guidelines set forth in VHA Handbook 1200.12[112], Use of Data and Data Repositories in VHA Research. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate. The Internet access to VINCI resources is approved in accordance with the above VHA Handbook, requirements of National Data Systems (NDS), and other applicable VA and VHA policies and regulations. VINCI maintains tight and consistent control over the standards and quality of the data. More information on the secure access to VINCI and how to use VINCI data is available online[113].

DoD And VA Infrastructure for Clinical Intelligence (DAVINCI)

As of September 2012, there were over 1,100 active VA and DoD research projects related to the health of deployed Service members and Veterans. Some investigators spent nearly two years obtaining needed project data. DAVINCI was funded by DoD in 2013 to provide centralized, integrated data and analysis platforms with appropriate security, policies, and governance for VA and DoD clinicians, researchers, administrators, and policymakers. When fully functional in 2015, DAVINCI will provide a mechanism for timely, secure sharing of data for both Departments. Long-term DAVINCI goals include the ability to conduct aggregate analysis across agencies in support of panel management, population health, improved delivery of queries, and reduced personnel and IT costs.

National-Level Data

Meet with the VA ISO and privacy officer early in project planning to discuss the logistics of the project. They will help you develop language to put into your protocol that will address VA data security concerns.

When national-level VA data with protected health information (PHI) are requested by a VA investigator, VA's Health Information Access Program[114] (HIA),

112. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1851
113. vaww.vinci.med.va.gov/vincicentral
114. vaww.vhadataportal.med.va.gov

available within VA, will conduct a privacy compliance review based on a submission package from the researcher. Once legal requirements (e.g., 38 USC 7332[115], the Privacy Act of 1974[116], and the HIPAA Privacy Rule[117]) have been satisfied through the privacy compliance review, the VA researcher will be provided with access to the information requested. The process of requesting and obtaining access to PHI can take six months or more, depending upon the completeness and complexity of the application.

DoD Data

A Military Health System (MHS) Guide for DoD Researchers on Using MHS Data[118] was developed in 2012 for DoD researchers who plan to request data, in particular for database research. It contains an overview of the MHS and the TRICARE Management Activity (TMA), guidance regarding the types of research data available within the MHS, reviews specific to the protection of human subjects, and requirements for requesting MHS data.

b. VA Data Agreements

Data Use Collection Agreements and Data Collection CRADAs are two types of agreements available for the exchange of VA data. There are special requirements associated with sharing restricted data with parties external to VHA. Examples of restricted information include VA Protected Health Information, and VA Sensitive Information or data. Such data may reside in data repositories developed for health care, administration of VA programs, or research. Use of such data must be consistent with the mission of VA: It must be relevant to the health of Veterans, protect the privacy of the individuals from whom the data are collected and comply with all applicable ethical and legal standards. Prior to the development of a written agreement between the provider and the recipient of the data, investigators must obtain approvals from their local IRB and R&D Committee. Other approvals may also be required, such as that of the Privacy Office, ISO, and any administrator or oversight committee of a specific data repository.

CRADA

The VA Technology Transfer Program (TTP), together with the Office of General Counsel, has developed a Data Collection CRADA template. This CRADA (see Section II.4.d of this guidebook) contains language that details the use and sharing of the research data, including a timeline of expected deliverables. In this context, "data" means recorded information first produced by the parties, as required in the performance of the protocol. TTP should be contacted for assistance in the development of this CRADA.

The Data Collection CRADA may be used for projects which meet all of the following criteria:

- The SOW calls for the retrospective or prospective collection of data from patient medical records or registries, through techniques such as data mining and outcomes analysis.
- The SOW does not call for any interaction with patients.
- No intellectual property is anticipated from the project, and neither party is interested in pre-commitment of intellectual property rights.
- The sponsor is not seeking individually identifiable information as defined in the agreement.

Additional information and model CRADA templates are available within VA at www.research.va.gov/programs/tech_transfer

Data Use Agreements (DUA)

These can be used to establish criteria for how data will be used, disclosed, stored, processed, and disposed of properly. They also identify who will have access to and control of the information. In summary, a DUA is an agreement that:

- governs the sharing of data between an information custodian and a user;
- establishes specific terms for VA or non-VA user uses, including protection for the confidentiality, integrity, and availability of the data, and the destruction or return of the data once the approved use is completed; and
- may need to be implemented when there is data sharing between a VA information custodian and a non-VA user, or between a VA user and a non-VA user. A DUA may not be required if there is a HIPAA authorization in place for disclosure.

Additional information and DUA templates are available within VA via the VHA Data Portal[119].

115. www.gpo.gov/fdsys/browse/collectiontab.action
116. www.justice.gov/opcl/privstat.htm
117. www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule
118. www.tricare.mil/tma/privacy/hrpp/downloads/Guide for DoD Researchers on Using MHS Data.pdf
119. vaww.vhadataportal.med.va.gov

VHA Handbook 1200.12[120] also imposes requirements for a DUA-DTA (Data Transfer Agreement) in certain circumstances. A VA DUA Handbook is currently in concurrence.

c. DoD Data Agreements

In some instances, particularly when the sharing activities are not too complex, a VA/DoD sharing agreement may be all that is needed for documenting the research activity. Such an agreement can also be used with an attached MOU for more complex arrangements. Please note, however, that all research approval protocols should be finalized before the sharing agreement is submitted.

TRICARE Management Activity (TMA) Data Sharing Agreement (DSA)

An executed TMA DSA, incorporating an approved Data Sharing Agreement Application[121] (DSAA), is used to document the TMA Privacy and Civil Liberty Office's confirmation of key data-sharing compliance points, including Privacy Act, HIPAA privacy and security requirements, and the Common Rule.

Requests for the use of TMA managed data (other than those involving MOU/MOA or CMA) are now submitted on a DSAA, which replaced the previously used Data Use Agreement (DUA) request templates. The approval of any DSAA follows a comprehensive review and assessment of the requested data in compliance with applicable DoD safeguards (see DoD 6025.18-R[122] "Department of Defense Health Information Privacy Regulation," January 24, 2003, and DoD 8580.02-R[123], "Department of Defense Health Information Security Regulation," July 12, 2007), including requirements for storage and destruction.

The following items are considered as appropriate:

- The frequency, amount, and type of data files requested are the minimum data necessary to perform the tasks outlined in the described project, according to DoD 6025.18-R[124].
- Data file access methods ensure all personally identifiable information (PII) and PHI are appropriately obtained.
- Information systems and networks intended for data processing and storage have appropriate physical, administrative, and technical safeguards, and data accessed from MHS systems of records are used in accordance with the purpose set forth in the corresponding System of Records Notice (SORN), as required by DoD 5400.11-R[125], "Department of Defense Privacy Program," May 14, 2007.
- Each DSAA received is accurate and complete. To be determined a "complete request," each application must include the following:
  (a) thorough responses, including applicant and government sponsor certifying initials;
  (b) a list of specific data elements required to perform contracted tasks (in accordance with the minimum necessary requirements of DoD 6025.18-R, "DoD Health Information Privacy Regulation") (In particular, requests for "all" data must be adequately justified;
  (c) TMA Human Research Protection Program[126] determination of an IRB-approved protocol or survey requiring TMA data, if the DSAA involves research (see the TMA HRPP web page);
  (d) TMA Privacy Board approval, if the protocol indicated in the DSAA involves the use of PHI; and
  (e) licensing approval from Washington Headquarter Services (WHS) or the Office of Management and Budget (OMB), if the project requires a survey.

Contractors seeking TMA data for any reason, and government personnel seeking to obtain MHS data for research purposes, may send a completed DSAA electronically to the TMA Privacy and Civil Liberties Office at DSA.Mail@tma.osd.mil, or a hard copy of the application and any supporting documentation may be mailed to the TMA Privacy and Civil Liberties Office, Attention: Data Sharing Compliance Manager, 7700 Arlington Boulevard, Suite 5101 Falls Church, VA 22042-5101.

A DSA is executed for one year, after which a DSA renewal request must be submitted to continue using the data.

Timely receipt of a Certification of Data Disposition (CDD) is required no later than 30 days after DSA expiration, or completion of a project, to confirm that the received data (including any derivative thereof) have been either destroyed or returned to the covered entity so that the business associate no longer has access to the data.

120. www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1851
121. www.tricare.mil/tma/privacy/downloads/2011Sep16/DSAA.pdf
122. www.dtic.mil/whs/directives/corres/pdf/602518r.pdf
123. www.dtic.mil/whs/directives/corres/pdf/858002rp.pdf
124. www.dtic.mil/whs/directives/corres/pdf/602518r.pdf
125. www.dtic.mil/whs/directives/corres/pdf/540011r.pdf
126. www.tricare.mil/tma/privacy/hrpp

Business Associate Agreement (BAA)

Contractors who provide services to DoD and receive or create PHI in performance of a service described in the HIPAA Privacy Rule must have a BAA incorporated into their contract, as required by DoD 6025.18-R, where appropriate. However, the BAA is not required for research unless the researcher is also performing functions of a BAA, as included in the Privacy Rule. For additional guidance, refer to 45 CFR Parts 160 and 164[127] and the Department of Health and Human Services (HHS) FAQ page[128] about business associate contracts.

Computer Matching Agreement (CMA)

A CMA defines the computerized comparison of two or more automated systems of records or a system of records with nonfederal records. Under the Privacy Act of 1974, as implemented by DoD 5400.11-R, no record contained in a system of records may be disclosed to a recipient agency or nonfederal agency for use in a computer matching program, except pursuant to a written agreement between the source agency and the recipient agency.

d. Data Retention Requirements

VA: At this point in time, all data collected in VA research studies must be maintained indefinitely by the VA facility.

DoD: Army CIP requires retention of study data (in hard or electronic form) for three years after study closure. HIPAA authorizations must be maintained for six years. Records from FDA-regulated studies must be maintained in accordance with FDA requirements[129].

Department of the Navy records are to be retained as specified in the DON Records Management Manual[130] (SECNAV M-5210.2).

In accordance with DoDI 3216.02, the Air Force retains records for at least three years after the research ends or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer.

7. Media Relations/Public Affairs

You may want to share information about your project with the public for recruitment purposes, or you may receive requests for information from your agency, your collaborator's agency, or from a public media outlet. Whatever the reason, it is essential to understand and anticipate the different issues, interests, and sensitivities regarding information and media relations in both departments and at the facilities where you are conducting your project.

If images of human subjects are to be shared outside of the study team, the appropriate consent for use of their likeness must be obtained in advance.

a. VA Policies

On the VA side, VHA Handbook 1200.19[131] explains the procedures, responsibilities, and authority needed to ensure that VA research contributions are appropriately acknowledged and publicly disclosed. The VA facility director or a designee, the R&D Committee, the R&D coordinator, VA Research Communications staff, and the investigator all have roles and responsibilities in this process. Failure to acknowledge VA support or employment as stipulated in the handbook may result in discontinuation of funding or, in extreme circumstances, may result in the revocation of the privilege to conduct research at VA.

Prior to any submission of research results for publication or presentation, investigators must submit the material to the locally designated review groups or individuals. This applies to all investigators, regardless of whether research support comes directly or indirectly from VA. Such support may be in the form of funding or resources, or as a result of compensated full-time, part-time, or WOC employment. As soon as an article or abstract is accepted for publication or presentation, the investigator or the local research office should inform VA Research Communications immediately (or

127. www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html
128. www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/239.html
129. www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126489.pdf
130. doni.daps.dla.mil/SECNAV%20Manuals1/5210.2%20(2012).pdf
131. www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1766

as soon as possible) by following the procedure outlined at vaww.ord.portal.va.gov/sites/comm/PubTracker/Pages/default.aspx.

VA Research Communications should also be notified regarding media interviews, or any other professional activities whereby research results are being publicized, presented, recognized, or discussed. In addition, your local VA public affairs office (PAO) should be notified about any activities with the potential for media attention. Check with your local PAO on the notification policy at your facility.

The acknowledgement of VA support or employment in your publications and, or during media interviews, is essential and may be achieved following different procedures depending on the type of presentation or event. Check VHA Handbook 1200.19 for specific requirements and guidelines. Here are examples:

- Acknowledgement of VA research support: In publications and presentations, incorporate the following (or equivalent) recognition: "This material is based upon work supported (or supported in part) by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development" (add specific research service as applicable).
- Acknowledgement of VA employment: In clinical and research manuscripts, abstracts, books, book chapters, and presentations, include acknowledgement by using the following format: "VA Title, VA Service, Department of Veterans Affairs Medical Center, City, State."
- VA acknowledgement in media reports: Provide news media, prior to interviews, with a document on VA letterhead containing: the investigator's name, title, and VA medical center; an explanation of VA's role in the research; and a request that the investigator's VA title be used if space or time permits the use of only one professional title.
- VA acknowledgement during other professional activities: Examples would include receiving an award or being appointed to a board.

U.S. Air Force Staff Sgt. Toni Thompson and Senior Airman Michael Urena inspect blood cells in the 354th Medical Group (MDG) laboratory at Eielson Air Force Base, Alaska. (Photo by Staff Sgt. Christopher Boitz)

- Disclaimer requirement: Publications or presentations must include a disclaimer stating that the contents do not represent the views of the Department of Veterans Affairs or the U.S. government.
- Publications by contractors: The publication of research results by firms providing contracted services to VA are governed by terms of the contract.

b. DoD Policies

On the DoD side, there is a two-pronged review process prior to the release of information. There are PAOs within each facility, and policies depend on the funding agency. Researchers must check with their relevant IRB and PAO before publication or other public dissemination of research-related material. DoD research must be vetted by Operational Security to ensure that no confidential or strategic intelligence is released to the public. It may also need to be reviewed by the PAOs at higher levels (such as BUMED). There are sensitive topic areas (e.g., TBI, PTSD, HIV, polypharmacy) that may require additional or closer review.

For the Army, signatures of all coauthors must be obtained prior to submission for publication. The clearance procedures differ by facility, and can involve approval by one or more of the following: research director, service chief, department chief, Department of Clinical Investigations/Human Subjects Protection Office, and PA Office (MTF or MRMC).

For the Navy, security review and approval is required prior to the release of any work authored by Navy Medical Department personnel. Authored works must be submitted to the publication officer, the PAO, and the author's chain of command for review and clearance before submission for publication or presentation. Other policies include the following:

- Navy publication approval: Procedures for obtaining publication or presentation approval for Navy researchers are covered by BUMED INSTRUCTION 5721.3C[132] and other related local command instructions.

132. www.med.navy.mil/directives/ExternalDirectives/5721.3C.pdf

- Acknowledgement of Navy research support: In publications and presentations, incorporate the following (or equivalent) recognition: "Research data derived from Study Title, an approved Naval Medical Center/Hospital XXX, IRB/IACUC protocol #."
- Acknowledgement of military identification or employment: In clinical and research manuscripts, abstracts, books, book chapters, and presentations, include author's name, rank (if applicable), department and command.
- Media reports: The PAO does not require written documentation, nor does it restrict the investigator to certain titles. However, all interviews must be coordinated through the PAO prior to the interview.
- Disclaimer requirement: Publications or presentations must include the following disclaimer: "The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government."
- Copyright statement requirement: Authors of official approved manuscripts cannot enter into any agreement that offers the publication exclusive rights. Government work, articles, and manuscripts prepared by government employees in the course of their official duties cannot be copyright-protected. Most publishers recognize this copyright limitation and may have alternative acknowledgments. If not, the following copyright statement must be attached to all authored works: "I am (a military service member) (an employee of the U.S. government). This work was prepared as part of my official duties." Title 17 USC 105[133] states that "copyright protection under this title is not available for any work of the U.S. government." Title 17 U.S.C. 101 defines a U.S. government work as a work prepared by a military service member or employee of the U.S. government as part of that person's official duties.

For the Air Force, collaborative research disclosures may describe proprietary information, human or animal research, or other potentially sensitive information that must be protected from inappropriate disclosure. Inappropriate disclosures may produce adverse public perceptions, complicate or prevent procurements or licensing efforts, or violate public laws. Air Force researchers and activities wishing to publically disclose a collaborative research or an invention resulting from the research must contact the AFMS ORTA before doing so.

c. Information Collections

VA: Data collection during research activities must also comply with non-research federal regulations such as HIPAA, FISMA, and the Paperwork Reduction Act. Surveys frequently fall under the Paperwork Reduction Act and therefore may require Office of Personnel Management (OPM) clearance.

DoD: Information collections may be internal to DoD, external (from members of the public), or interagency (between federal agencies). For examples of licensed information collections, see DoD 8910.1-M[134].

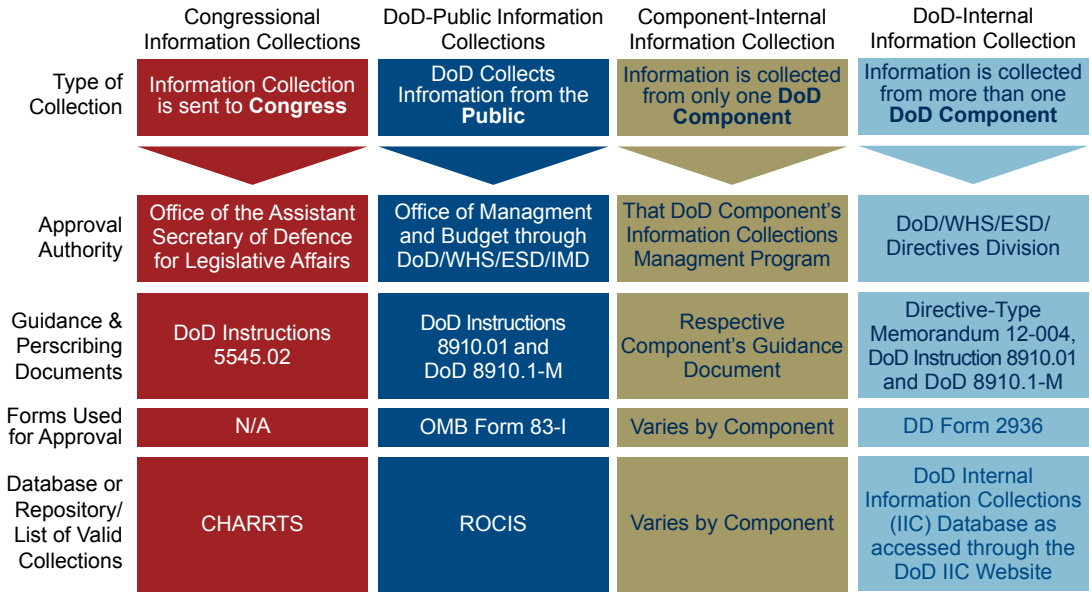


Figure 10: Types of Information Collections

133. www.copyright.gov/title17/92chap1.html

134. www.dtic.mil/whs/directives/corres/pdf/891001m.pdf

If a research project will include focus groups, surveys, questionnaires, or other opinion-gathering media, additional approvals may be needed before the work can begin, as governed by 10 USC 88, S1782, DODD 8910.01, DOD 8910.1-M, DODI 1100.13, and DODI 5545.02. These policies comply with the requirements outlined in the Paperwork Reduction Act (PRA) of 1995. Office of Management and Budget (OMB) information and updates on federal information collection is available at www.whitehouse.gov/omb/inforeg_infocoll.

There are four types of information collections, as depicted in Figure 10. Each pathway has its own level of approval authority, policy and guidance documents, forms, and timelines. With approval pathways ranging from Service Component Information Collections Management Program Offices for single-service information, to the OMB for public information collections, timelines can range from 3 to 24 months. If you are considering these media as a part of your project, consult the appropriate approval authority office as soon as possible to start the approval process concurrent to your grant proposal, IRB, CRADA, or DSA processes.

8. The Future of VA/DoD Research Collaboration

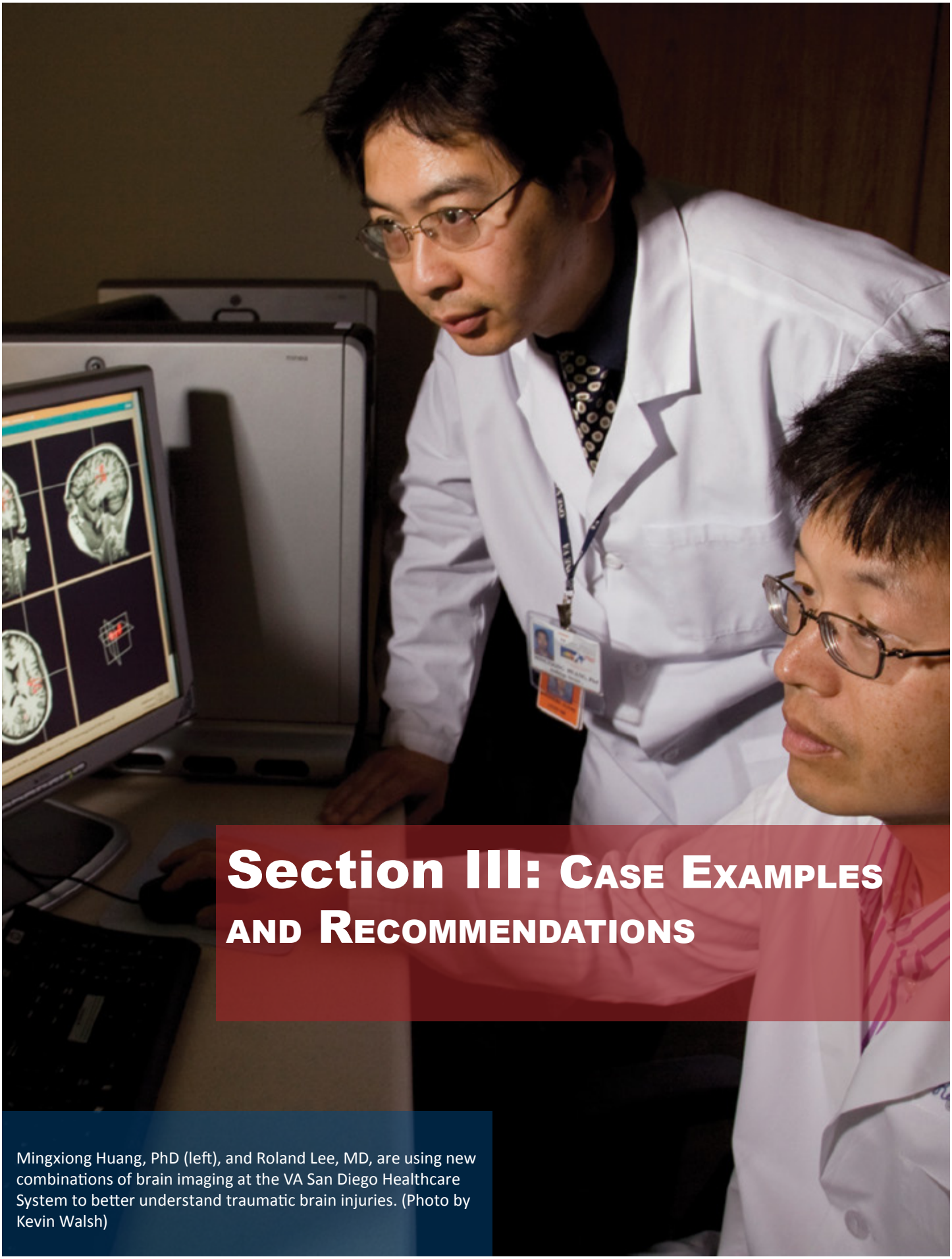
National Research Action Plan

In response to the President's August 2012 executive order directing federal agencies to develop a coordinated National Research Action Plan, DoD and VA, along with the Department of Health and Human Services and the Department of Education, came forward in August 2013 with a wide-reaching plan to improve scientific understanding, treatment, and prevention of PTSD, TBI, co-occurring conditions, and suicide. The plan includes the establishment of two new joint DoD/VA research consortia by March 2014. The Consortium to Alleviate PTSD (CAP), a collaboration between the University of Texas Health Science Center – San Antonio, San Antonio Military Medical Center, and the Boston VA Medical Center, will seek to discover and develop biomarkers. The Chronic Effects of Neurotrauma Consortium (CENC), a collaboration among Virginia Commonwealth University, the Uniformed Services University of the Health Sciences, and the Richmond VA Medical Center, will study the links between concussions, chronic mild TBI, neurodegeneration, and comorbidities.

By August 2014, it is expected that:

- Researchers will develop a more precise system for classifying and staging TBI that will enhance the accuracy of diagnosis and the selection of effective treatments by clinicians.
- Agencies will work together to increase and coordinate their inventory of scarce resources, facilitate research access, and preserve patient confidentiality.
- Agencies will create common data elements (CDEs), to be used across studies and across agencies and will expand upon the previous success of the CDE approach to advance PTSD and suicide research.
- Agencies will continue to fund innovative research for the President's BRAIN Initiative (Brain Research through Advancing Innovative Neurotechnologies).
- NIH and DoD will build on their collaborative, comprehensive Army STARRS study, including 100,000 Service members, to assess how longitudinal follow-up can define risk and resilience for suicide.
- Scientists will perform ongoing coordinated research portfolio analyses of existing and emerging diagnostics, therapeutics, and outcome measures.
- Agencies will unite all facets of research, from basic science to clinical trials, to follow-up care, toward a common goal.

Longer-range goals include determining genetic markers, identifying changes in brain circuitry, confirming potential biomarkers, and establishing data-sharing agreements.



Section III: Case Examples and Recommendations

Mingxiong Huang, PhD (left), and Roland Lee, MD, are using new combinations of brain imaging at the VA San Diego Healthcare System to better understand traumatic brain injuries. (Photo by Kevin Walsh)

a. Case Examples and Cautionary Tales

We hope you find this guidebook helpful in planning your next VA/DoD research collaboration. As you've learned, the process can be complex, but the potential benefits for healthcare systems, Service members, and Veterans are well worth the effort.

The following vignettes present examples of successful research collaboration, as well as cautionary tales. These case examples are provided to illustrate some of the key components of research collaboration that were discussed in this guidebook.

Project:
DElivery of Self-TRaining & Education for Stress Symptoms-Primary Care version (DESTRESS-PC)

Principal DoD investigators:
COL Charles Engel, MD, MPH, MC, USA, DoD Deployment Health Clinical Center (DHC), Walter Reed National Military Medical Center (WRNMMC) and Uniformed Services University of the Health Sciences (USU)

Collaborating VA investigators:
Kathryn Magruder, PhD, Charleston VA and Medical University of South Carolina; and
Brett Litz, PhD, Boston VAMC and Boston University

Funding agencies involved:
DoD, National Institute of Mental Health (NIMH)

Project period:
Five years from planning to completion

2013 status:
Project is closed. Investigators are preparing papers for submission to peer-reviewed journals and making some scientific presentations

COL Charles Engel, director of the DoD Deployment Health Clinical Center at Walter Reed National Military Medical Center, has promoted the improvement of mental health services in primary care for Service members through clinical programs, research, and outreach for over 15 years. In line with these efforts and in collaboration with VA researchers Drs. Magruder and Dr. Litz, COL Engel initiated the DESTRESS-PC trial to test a Web-based self-management tool designed for use in primary care patients with symptoms of PTSD. The trial was developed as a collaborative research effort crossing both DoD and VA healthcare systems, using Womack Army Medical Center and the Charleston VA as data collection sites, to improve primary care mental health services for both military personnel and Veterans with PTSD related to war-zone trauma. The combined expertise of COL Engel, Dr. Magruder, and Dr. Litz resulted in a protocol with maximum population reach and regard for each system's particular strengths, particularly the VA system's greater stability, which maximizes the opportunity for primary care continuity and successful mental health intervention, and the DoD system's greater opportunity for earlier intervention and wider coverage of returning troops.

The DESTRESS-PC trial received dual funding from both DoD and NIMH mechanisms, which presented a unique set of challenges. The regulatory process was delayed by a year so the study methodology could be expanded to encompass both sets of funding, and also so the respective budgets and statements of work could be revised to ensure that no funds were overlapping. The dual funding and multisite nature of the study also caused a delay in the approval of two CRADAs for the study.

The DoD/VA collaboration also presented start-up challenges in terms of determining which IRB would serve as the IRB of record (and developing a memorandum of understanding), undergoing multiple regulatory reviews with differing standards and requirements, and developing data use and transfer agreements between organizations.

Due to these administrative delays, recruitment for the DESTRESS-T trial started a year behind schedule, and enrollment rates were initially lower than expected. Several protocol modifications, including increasing the number of clinics involved in recruitment, distributing advertisements, and holding clinic briefings, were approved by DoD/VA IRBs to improve recruitment. Additionally, multiple no-cost extensions were requested and approved, allowing for continued enrollment beyond the original schedule. Despite initial delays and almost a full year of no-cost extensions, a sufficient sample was enrolled to allow for statistical analyses. Since the intervention is good for patients who would otherwise have to travel great distances for care, one VA site was able to use one of its community-based outpatient clinics to recruit patients.

The DESTRESS-PC study benefited from the strong DoD and VA networks developed by the PIs. The identification of engaged site PIs and the development of rapport with site personnel also proved to be of utmost importance to the successful completion of this study. As "on the ground" assets, site PIs served as study advocates and were able to secure office space and troubleshoot logistical issues. Site PIs also played a crucial role in increasing study awareness and promoting referral among clinic staff. Patients at VA sites are more geographically distributed than those at DoD sites.

Project:
Caring Letters for Military Suicide Prevention: A Randomized Controlled Trial

Principal investigator:
David Luxton PhD, DoD National Center for Telehealth & Technology (T2), Joint-Base Lewis-McChord and Madigan Army Medical Center (MAMC)

Collaborating DoD Investigators:
Helenna Nakama, MD, Tripler Army Medical Center (TAMC);
Daphne Brown, PhD, Landstuhl Regional Medical Center (LRMC);
Robert McLay, MD, PhD, Navy Medical Center San Diego (NMCSD)

Collaborating VA investigators:
Tina Lee, MD, and. Rona Relova, MD, Palo Alto VA Healthcare System;.
Joan Chipps, LCSW-R, Western New York VA Healthcare System;
Janet Kemp, RN, PhD, VA National Suicide Prevention Coordinator

Funding agency involved:
Military Operational Medicine Research Program (MOMRP)
Assisted by: Geneva Foundation, Palo Alto Institute for Research and Education (PAIRE)

Project period:
Planning started in 2008, full proposal submitted in 2010, funding awarded 2011, ongoing

2013 status:
Recruiting patients

The caring letters concept is a suicide prevention intervention that involves the routine sending of brief caring messages to patients following hospital discharge. First tested in the 1970s, it is the only intervention shown in a randomized controlled trial to reduce suicide mortality rates. Given the elevated risk for suicide among post-hospitalized psychiatric patients, as well as the rising rates of suicide among military Service members, the decision to evaluate this intervention within both the DoD and VA healthcare systems was a logical one.

The study sites include four DoD military treatment facilities and two VA healthcare centers. The participating sites for the trial were selected because they had sufficient size of the inpatient units (to meet recruitment goals) and no concurrent studies or procedures that would have interfered with study recruitment or objectives.

The current study is a five-year randomized controlled trial that tests the caring letters intervention (updated by sending emails instead of postal letters) at military and VA medical treatment facilities. Up to 4,730 patients are being recruited from inpatient psychiatry units across the six participating sites. A trained research assistant who is "embedded" in each site's inpatient treatment unit is responsible for carrying out the protocol. The inpatient psychiatry unit staff at each site is instrumental in referring patients and assisting with the protocol. Following informed consent procedures, patients complete a semi-structured psychosocial interview with the research assistant and are then randomized to either a group that receives caring emails (13 contacts for two years) or a usual-care group (no additional contact). Each email also includes a reminder of available help resources (e.g., the Veteran's Crisis Line). Suicide mortality rates in both groups will be examined at the end of two years, along with rates of behavioral health utilization, suicide attempts, and rehospitalizations.

Planning for this project began in 2008. A pilot study was first conducted at MAMC to test procedures and feasibility. The full grant proposal was submitted in early 2010, and funding for the trial was awarded in early 2011. The research protocol was first submitted to the MAMC IRB within 30 days and was approved by October 2011. The next step was review by the DoD Human Research Protection Office (HRPO) and then IRB submission at the other participating sites. It took a total of 21 months to have all sites approved. The IRB process at the DoD sites took longer than anticipated (8 to 13 months), whereas the review and approval process at the two VA sites occurred within three months. Although the delay caused by the complex IRB/regulatory process set the team behind on planned recruitment goals, all sites are actively enrolling patients at a steady pace.

This trial is logistically complex, with multiple IRBs (both DoD and VA) as well as multiple locations and time zones in the U.S. and abroad (LRMC). Coordination and synchronization with each of the sites regarding local regulatory requirements and procedures is essential. The site PIs found it helpful to meet to discuss local requirements before IRB submissions. Centralization of data management and materials at the main coordinating site (T2) has also been particularly helpful: A centralized database was created and all research materials and standardized training is provided by the main coordinating site.

Training consists primarily of required readings, review of a study manual, informed consent process, and

interview procedures practice. The protocol training is provided both remotely via teleconferencing and email and by on-site staff.

The Geneva Foundation provides the personnel and grant administrative support for the military sites and one VA site (Western New York). The Palo Alto Institute for Research and Education (PAIRE) provides this support at the other VA site. Several of the sites (Palo Alto, NMCSD, TAMC, and MAMC) have also made presentations at local and national conferences regarding the implementation of the trial and implications for suicide prevention in the VA and DoD healthcare systems. This has helped to bring the teams together, share lessons learned, and communicate to stakeholders the benefits of this intervention.

Should this simple and inexpensive intervention prove effective, it could be used to help prevent suicides among Service members and Veterans following treatment in all care settings that encounter patients at risk for suicide.

Project:
DoD/VA Trauma Infectious Disease Outcome Study (TIDOS)

DoD principal investigator:
David Tribble, MD, DrPH, Science Director, Infectious Disease Clinical Research Program (IDCRP), and professor, USU

VA collaborating investigator:
Jay McDonald, MD, Chief, Infectious Diseases, St. Louis VAMC

Other collaborating agencies involved:
National Institutes of Health (NIH)

Funding agencies involved:
U.S. Navy BUMED Wounded, Ill, and Injured Program, the National Institute of Allergy and Infectious Diseases (NIAID), the DoD Global Emerging Infections Surveillance and Response System, and the Defense Health Program (US Army DMRDP)

Project period:
June 2009 - ongoing

2013 status:
Enrolling subjects, analyzing and reporting findings

The significant advances leading to survival of combat-related injuries in the military conflicts in Iraq and Afghanistan have come with major challenges in post-injury medical care due to frequent severe polytrauma with extensive wound contamination and risk for infectious complications, including multidrug-resistant pathogens. A 2006 IDCRP DoD and NIH National Institute of Allergy and Infectious Diseases (NIAID) gap analysis identified this priority issue and recommended increased efforts to prevent infection related to combat injury.

Despite a growing body of literature on the subject, the limited prospectively collected standardized infection data on specific therapy by date, microbiological findings, and clinical outcomes across treatment facilities led to development of the DoD Trauma Infectious Disease Outcome Study (TIDOS) by Dr. Tribble at USU and colleagues across DoD hospitals caring for wounded warriors. The DoD patients who would be recruited for the TIDOS study often quickly transitioned to VA medical care and the long-term outcomes would almost always be seen on the VA side. Cross-agency collaboration on this study would be a benefit for collecting longitudinal data that could improve immediate post-injury medical care.

Concurrently, Dr. McDonald at the St. Louis VAMC had applied for and received funds from Veterans Integrated Service Network (VISN) 15 for a two-year study to investigate osteomyelitis. Due to his interest in the long-term consequences of combat-injured patients who are still receiving treatment when they enter VA care, he wanted to work with WRAMC. Dr. McDonald mentioned this to a DoD colleague who connected him to Dr. Tribble. After some discussion and an in-person meeting, a DoD/VA TIDOS collaboration was proposed.

In 2007-08, the proposal and multisite MOU were developed at DoD using the centralized scientific and central IRB protocol review process, which greatly enhances DoD investigators' ability to engage in multicenter clinical research. The MOU signed by the president of USU and the Deputy Assistant Secretary of Defense for Force Health Protection & Readiness established an infectious disease IRB and a TriService and Under Secretary of Defense for Personnel & Readiness headquarters-level panel to streamline the scientific and ethical review and approval process. The protocol was submitted in August 2008 and the total approval process took four to five months, including much back and forth regarding the scientific review. The DoD component of the project was approved by the USU central IRB for all DoD activities, and the study commenced in June 2009.

Even after face-to-face meetings at VA Central Office and appeals to VA leaders, Drs. Tribble and McDonald were unable to secure VA approval to use DoD-obtained study consent for use in VA research. As a result, the

TIDOS protocol was not approved by the VA IRB until June 2010, after the investigators agreed to a second consent process for VA. The one-year approval period after the DoD study start date was further compounded by the requirement to obtain documented consent through mailings and phone interviews. These factors have delayed VA data collection for three years.

A request to waive the VA informed-consent documentation process during the phone interviews was approved this year. The VA TIDOS team is now consenting TIDOS subjects who have entered VA care, and has successfully enrolled about 50% of all potential study subjects who have been sent information and consent packets, with very few hard refusals (7-8%). This modified process has been helpful, although there is still a 40-50% loss to follow-up within VA that perhaps could have been avoided if a joint single informed-consent process for both DoD and VA follow-up had been permitted at initial cohort enrollment. The investigators expect to complete attempting the VA consent process with the majority of DoD enrollees by March 2014. The VA research team uses the Compensation and Pension Record Interchange (CAPRI) system to run through data sets to see who has been enrolled in DoD TIDOS and to extract and abstract infectious disease events. The DoD TIDOS phone follow-up model has now been adapted for VA use. Dr. McDonald and his team are working with their DoD colleagues to identify events, correlate care, and predict outcomes.

Dr. McDonald credits Dr. Tribble with securing the funding needed to get the collaboration up and running from multiple sources (Navy BUMED, NIAID, and Army). He plans to apply for intramural VA funding as well. He suggests that others interested in collaborative projects should just "dive in" and keep the lines of communication open. He says he perceived barriers to collaboration to be larger than they were, and that he feels "rewarded by the excitement of a study that will save lives and change how soldiers are treated in the field." Key ingredients identified by Dr. McDonald and his team that keep the collaboration working well include:

- maintaining professional, friendly, and collaborative attitudes with DoD personnel;
- using uniform talking points with study patients who will transition from DoD to VA;
- holding regular monthly conference calls and periodic in-person meetings to maintain energy and focus;
- knowing whom to contact for specific needs (data management, IRB, protocol deviations, etc.);
- staying open to the many changes that come as part of any study;
- helping the DoD with specific, line-by-line instructions on how to set up and take VA trainings;
- getting to know the site coordinators personally and letting collaborators know they can contact each other directly to discuss details not covered in the group calls;
- knowing each other's deadlines and barriers; and
- making sure everyone knows it's okay to ask if they are unclear about something.

Project:
A Brief Intervention to Reduce Suicide Risk in Military Service Members and Veterans

Principal DoD investigators:
Marjan Holloway, PhD, associate professor of medicine and clinical psychology, USUHS, Bethesda, MD

Collaborating VA investigators:
Lisa Brenner, PhD, VA VISN 19 MIRECC, Denver and University of Colorado; Gregory Brown, PhD, VA VISN 4 MIRECC and University of Pennsylvania; Glenn Currier, MD, MPH, and Kerry Knox, PhD, VA Center of Excellence, Canandaigua and University of Rochester; Barbara Stanley, PhD, Columbia University

Funding agencies involved:
DoD Military Operational Medicine Research Program

Project period:
Project submitted May 2009; funded September 2009; ongoing

2013 status:
No cost extension, data analysis phase in 2014

The frequency of suicide in DoD Service members and Veterans increased during the last decade and is an urgent concern for both VA and DoD. Several VA investigators concerned about the increasing rates of suicide in Veterans began discussions on a safety planning intervention for suicide prevention. In 2008, Drs. Stanley and Brown developed a brief clinical intervention titled "Safety Planning" for use by mental health clinicians across the VA behavioral health treatment spectrum. When DoD released a related funding announcement, the investigators, realizing the urgent need within VA and DoD, began discussions with their former colleague, Dr. Holloway—now at Walter

Reed National Military Medical Center—and with colleagues in other VA settings about a collaborative research study.

The resulting VA/DoD research collaboration includes two projects that adapt and evaluate a brief, readily accessible, and personalized intervention titled Safety Planning, consisting of 1) evaluating suicide risk using a structured assessment measure, 2) enhancing suicide-related coping strategies and 3) increasing acceptability and initiation of appropriate mental health and substance use treatment. The first project, titled SafeMil, a randomized controlled trial to test efficacy, is being conducted among inpatients at Walter Reed National Military Medical Center. The second, SafeVet, is a quasi-experimental design to test the effectiveness of the safety plan in Veterans making emergency department visits at eight VAMCs. Both projects have multiple outcome measures that include assessing suicide ideation and suicide-related coping. Upon the projects' completion, positive findings will be implemented in both agencies.

The time frame to develop and submit this proposal was weeks. There was a four-month interval between submission, response to reviewers and funding. It took two years for the investigators to address the requirements of 19 different IRBs before they could begin subject enrollment. This regulatory challenge resulted in the investigators' falling behind on the project timeline as initially proposed. Additional resources were requested and received from the sponsor to better manage this administrative load.

Another challenge was the credentialing of study clinicians, which within DoD is often lengthy and may require more than six months. VA clinicians, as well, often experience delays in the credentialing process. For this project, however, while the credentialing of study staff at Walter Reed was very lengthy, the VA study staff were largely already employed within the system. Cost accounting allowed the study to pay for the therapists' research time.

This research collaboration builds on strong, existing professional relationships, which helped with the development of a number of elements to ease the process:

- At the outset the joint PIs decided on the leadership plan, so it was clear that each PI at each site had a shared decision-making authority.
- A multiple PI mechanism was used. Roles were clearly defined for other involved team members.
- Twice weekly, or weekly at later stages of the research, a conference call of all PIs provided consistent opportunities for coordination of research efforts wherein PIs discussed subject, enrollment, study progress, and special challenges. Meeting minutes documented decisions made by the investigators.
- Allowance for an IRB coordinator for the project freed up investigators' time for other study-related activities. In addition, one person was left in charge of overseeing the coordination of regulatory requirements for the study across 19 institutional, VAMCs, and DoD IRBs.
- Attendance and presentations at annual VA/DoD suicide prevention conferences helped the investigators with face-to-face communications and dissemination of information to professional colleagues and DoD/VA leadership.

b. Recommendations

VA and DoD investigators stand ready and willing to collaborate. Despite the challenges and complexities, some research teams have been successful. Other collaborative projects remained unable to take flight, because of insurmountable barriers. Our authors, contributors, and reviewers worked together to share the benefits of their experiences. Many suggested ways that VA and DoD could work together to remove barriers and facilitate collaboration. We have summarized key recommendations below. Some of these recommendations are targeted to local research administration, while others will need to be addressed through collaborative efforts of VA and DoD national leadership.

- Provide for wide dissemination of this Research Collaboration Guidebook and provide future resources to update the guidebook at regular intervals.
- Foster scientific exchange through jointly sponsored scientific meetings, conferences, and events.
- Work within departments to enable VA and DoD to recognize the authority of each other's IRB as the IRB of record, or create a separate IRB with authority to approve VA/DoD studies. This will reduce confusion and redundancy and increase efficiency
- The move to IRBnet within DoD has been under way, but many other institutions, including VA, aren't on IRBnet. This makes navigating the IRB process more difficult as procedures differ from institution to institution. This process need to be streamlined.

- All IRBs need a website with clear guidelines for submission, timelines for review, list of contacts and their roles.
- Develop overarching MOUs to facilitate potential research collaborations, ensuring that these are broadly written to facilitate collaboration rather than limit it.
- Develop mechanisms to facilitate exchange of VA and DoD clinical and research data through umbrella agreements, new policies, and innovative mechanisms.
- Disseminate model agreements for VA/DoD CRADAs, IAAs, and MOAs for interagency studies.
- Create a CRADA process flow chart to help determine if a CRADA is needed and post to a centralized location.
- Devise a way to combine the credentialing process, or add a research credentialing process for multisite and VA/DoD studies.
- Create a centralized database of VA/DoD collaborators that has the ability to cross-reference by interests, experience, and location.
- Provide opportunities for scientific review prior to research proposal submission and IRB protocol submission. This will assist new investigators in navigating scientific and human subjects issues.
- Work with stakeholders to recognize the unique role of VA in following Service members from separation from active duty through the remainder of their lifespan.
- Facilitate greater involvement of VA researchers in the DoD scientific review process and greater involvement of DoD researchers in the VA scientific review process to improve understanding of and participation in bi-agency research.
- Develop umbrella contracts for research services provided at the military treatment facilities to enable greater efficiency in the contracting process.
- Prioritize the funding of collaborative research projects.
- Work to harmonize existing VA and DoD regulations pertaining to research.
- Support policies to enable travel, and provide funds for collaborators to meet in person for planning, conduct, and reporting of research.
- Offer small grants for research planning purposes to allow investigators to meet with potential collaborators, administrators, and leadership, thus setting the stage for successful research proposal planning.
- Develop a DoD/VA coordinated approach to the informed-consent process to facilitate longitudinal studies.

Endnotes

i Pub. L. 108–375[a], div. B, title XXVIII, § 2811, Oct. 28, 2004, 118 Stat. 2128[b]
   a. www.law.cornell.edu/usc-cgi/get_external.cgi?type=pubL&target=108-375
   b. www.gpo.gov/fdsys/pkg/STATUTE-118/html/STATUTE-118-Pg1811.htm

ii 10 USC 2514 - Encouragement of technology transfer
   www.gpo.gov/fdsys/granule/USCODE-2010-title10/USCODE-2010-title10-subtitleA-partIV-chap148-subchapIII-sec2514/content-detail.html

iii dmrdp.dhhq.health.mil/about_dmrdp/About.aspx

iv dmrdp.dhhq.health.mil/researchprogram/researchprogram.aspx

v dmrdp.dhhq.health.mil/about_dmrdp/process.aspx

vi 10 USC 2113
   www.gpo.gov/fdsys/pkg/USCODE-2012-title10/pdf/USCODE-2012-title10-subtitleA-partIII-chap104-sec2113.pdf

vii 15 USC 3710a
   www.gpo.gov/fdsys/pkg/USCODE-2012-title15/pdf/USCODE-2012-title15-chap63-sec3710a.pdf

viii VA Handbook 7127/4 Materiel Management Procedures
   www.va.gov/vapubs/viewPublication.asp?Pub_ID=277&FType=2

ix OMB A-21
   www.whitehouse.gov/omb/circulars_a021_2004

Appendices

U.S. Air Force Senior Airman Monik Williams, a lab technician, analyzes a blood sample using the VITROS 350 Chemistry Analyzer, at a clinic at Randolph Air Force Base, Texas in 2010. (Photo by Don Lindsey)

Appendix A

VA/DoD Research Collaboration Abbreviations, Acronyms, and Initialisms

(VA terms are in italics, DoD terms are in bold, and terms that apply to both agencies are in regular type)

AAHRPP	Association for the Accreditation of Human Research Protection Program
AAMTI	**AMEDD Advanced Medical Technology Initiative**
ACO	**Administrative Contracting Officer**
ACOS	Associate Chief of Staff
ACTD	**Advanced Concept Technology Demonstrations**
ACURO	**Animal Care and Use Review Office**
ADP	**Automated Data Processing**
ADR	**Adverse Drug Reaction**
AF	**Air Force**
AF/SGR	**Air Force Surgeon General, Directorate for Research and Acquisition**
AFB	**Air Force Base**
AFMS	**Air Force Medical Service**
AFMSA	**Air Force Medical Support Agency**
AFOSR	**Air Force Office of Scientific Research**
AFRIMS	**Armed Forces Research Institute of Medical Sciences**
AFRL	**Air Force Research Lab**
AFSG	**Air Force Surgeon General**
AHLTA	**Armed Forces Health Longitudinal Technology Application**
AHRPO	**Army Human Research Protection Office**
AKO	**Army Knowledge Online**
AMC	**Army Medical Center**
AMEDD	**Army Medical Department**
ANG	**Air National Guard**
AO	*Administrative Officer*
AO	**Action Officer**
AOR	Authorized Organizational Representative
ARA	Applied Research Associates, Inc.
ARL	**Army Research Laboratory**
ART	**Annual Report Template**
ASAALT	**Assistant Secretary of the Army for Acquisition, Logistics & Technology**
ASDHA	**Assistant Secretary of Defense for Health Affairs**
ATO	**Authorization to Operate**
BA	**Budget Activity**
BAA	Business Associate Agreement (also see following entry)
BAA	**Broad Agency Announcement**
BAG	**Budget Activity Group**
BLR&D	*Biomedical Laboratory Research & Development Service*
BRAC	**Base Realignment and Closure**
BRAIN	Brain Research through Advancing Innovative Neurotechnologies
BUMED	**Bureau of Medicine and Surgery**
CAC	**Common Access Card**
CAGE	Commercial and Government Entity
CAREN	**Computer Assisted Rehabilitation Environment**
CAP	Consortium to Alleviate PTSD
CAPE	**Case Assessment and Project Evaluation**
CBOC	*Community-Based Outpatient Clinic*
CCR	Central Contractor Registry
CDD	**Certification of Data Disposition**
CDE	Common Data Elements
CDMRP	**Congressionally Directed Medical Research Programs**
CDW	*Corporate Data Warehouse*
CENC	Chronic Effects of Neurotrauma Consortium
CFI	**Center for the Intrepid**
CFR	Code of Federal Regulations
CGE	*Concur Government Edition*
CGMP	Current Good Manufacturing Practices
CHAMPUS	**Civilian Health and Medical Program of the Uniformed Services**
CHAMPVA	**Civilian Health and Medical Program of Veterans Affairs**
CHARRTS	*Congressional Hearing and Reporting Requirements Tracking System*
CID	**Clinical Investigation Department (Navy)**
CIO	Chief Information Officer
CIP	**Clinical Investigation Program**
CIPRS	*Center for Implementation Practice and Research Support*
CIRB	*Central Institutional Review Board*
CIRO	**Clinical Investigations Regulatory Office**
CITI	Collaborative IRB Training Initiative
CMA	**Computer Matching Agreement**
CO	*Central Office*
COACH	**Center on Advice and Compliance Help**
COE	Center of Excellence
COI	Conflict of Interest

CONOPS	**Concept of Operations**
COS	Chief of Staff
CPRS	Computerized Patient Record System
CR	Contract Representative
CRADA	Cooperative Research and Development Agreement
CRADO	*Chief Research and Development Officer*
CRD	**Clinical Research Division (Air Force)**
CSI	**Congressional Special Interest**
CSP	Cooperative Studies Program
CSR&D	*Clinical Science Research & Development Service*
CTM	*Clinical Trial Monitor*
DARPA	**Defense Advanced Research Project Agency**
DAVINCI	DoD and VA Infrastructure for Clinical Intelligence
DCI	**Department of Clinical Investigation (Army)**
DCC	Data Consent Committee (HIPAA abbreviation)
DCO	**Defense Connect Online**
DCoE	Defense Center of Excellence for Traumatic Brain Injury/Psychological Health (TBI/PH)
DDR&E	**Director of Defense Research & Engineering**
DFARS	**Department of Defense Federal Acquisition Regulation Supplement**
DHA	**Defense Health Agency**
DHHS	Department of Health and Human Services
DHP	**Defense Health Program**
DHS	Department of Homeland Security
DHSP	**Division of Human Subjects Protection**
DIF	**De-Identified**
DMC	*Data Monitoring Committee*
DMDC	**Defense Manpower Data Center**
DMRDP	**Defense Medical Research and Development Program**
DoD	Department of Defense
DoDGAR	**Department of Defense Grant and Agreement Regulations**
DoN	**Department of Navy**
DoN HRPP	**Department of the Navy Human Research Protection Program**
DRA	Designated Research Area
DRE	Designated Research Elements
DRP	**Department of Research Programs**
DRS	**Data Repository System**
DSA	**Data Sharing Agreement**
DSAA	**Data Sharing Agreement Application**
DSMB	*Data Safety and Monitoring Board*
DSMO	Designated Standard Maintenance Organization (HIPAA abbreviation)
DSS	*Document Storage Systems*
DTA	*Data Transfer Agreement*
DTIC	**Defense Technical Information Center**
DTRA	**Defense Threat Reduction Agency**
DUA	*Data Use Agreement (now* **DSA** *for DoD)*
DUNS	Data Universal Number System
DVA	Department of Veterans Affairs
DVBIC	**Defense and Veterans Brain Injury Center**
EACE	DoD/VA Extremity Trauma and Amputation Center of Excellence
EHR	**Electronic Health Record**
EIL	*Equipment Inventory Listing*
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ePROMISE	*Electronic Project Management and Information System*
F&A	*Facilities & Administrative*
FAAN	Fellow of the American Academy of Nursing
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FEGLI	Federal Employees Group Life Insurance
FEHB	Federal Employees Health Benefits
FFP	Fabrication, Falsification and Plagiarism
FFRDC	Federally Funded Research and Development Center
FHP&R	**Force Health Protection & Readiness**
FISMA	Federal Information Security Management Act
FMS	Financial Management Act
FTEE	Full-time Employee (FTE) Equivalent
FY	Fiscal Year
G&A	*General & Administrative*
GAO	Government Accountability Office
GCP	Good Clinical Practice
GEAR	*Graduate Education & Research Center*
GLP	Good Laboratory Practice
GME	Graduate Medical Education
GS	General Schedule
GTMR	Greater than Minimal Risk
HA	**Health Affairs**
HCE	Hearing Center of Excellence
HCP	Healthcare Provider

Appendix A

HEDIS	*Healthcare Effectiveness Data & Info Set (trademarked)*
HERC	*Health Economics Resource Center*
HHS	Department of Health and Human Services
HIA	*Health Information Access*
HIPAA	Health Insurance Portability and Accountability Act
HIPDB	Health Integrity and Protection Data Bank
HLAR	**Headquarters-Level Administrative Review**
HQ	**Headquarters**
HRPO	**Human Research Protections Office**
HRPO	**Human Research Protection Official (Air Force)**
HRPP	Human Research Protection Program
HS&FO	**Health Science & Force Optimization**
HSPS	Human Subject Protections Scientist
HSR	**Health Services Research**
HSR&D	*Health Services Research & Development*
HSRP	**Human Subjects Research Protection**
HSRRB	**Human Subjects Research Review Board**
HSRS	Human Subjects Research Subcommittee
HURC	Human Use Review Committee
IAA	Interagency Agreement
IACUC	Institutional Animal Care and Use Committee
IAIR	Institutional Agreement for IRB Review
IATO	**Interim Authorization to Operate**
IDE	Investigational Device Exemption
IIR	*Investigator Initiated Research*
IMCO	**Information Management Control Officer**
IMD	**Information Management Directorate**
IND	Investigational New Drug
IO	Institutional Officer
IP	Integration Panel, Intellectual Property
IPA	Intergovernmental Personnel Act
IPO	DoD/VA Interagency Program Office
IRB	Institutional Review Board
IRBO	Institutional Review Board Office
IRM	Information Resources Management
ISO	*Information Security Officer*
ISR	**Institute of Surgical Research**
IT	Information Technology
J&A	Justification and Approval
JEC	VA/DoD Joint Executive Council
JFHP	**Joint Force Health Protection**
JIF	Joint Incentive Fund
JPC	**Joint Program Committee**
JRRD	Journal of Rehabilitation Research and Development
JFCOM	**Joint Forces Command**
JPRP	Joint Programmatic Review Panel
JSLIP	Joint Senior Leadership Integration Panel
JTF	**Joint Task Force**
JTF CapMed	**JTF National Capitol Region Medical Command**
LaRC	**Langley Research Center**
LAR	Legally Authorized Representative
LDS	Limited Data Set
LOI	Letter of Intent
LSI	Local Site Investigator
LTC	**Lieutenant Colonel**
MCD	*Medical Center Director*
MEDCOM	**Medical Command**
MHS	**Military Health System**
MIPR	**Military Interdepartmental Purchase Request**
MOA	Memorandum of Agreement
MOMRP	**Military Operational Medicine Research Program**
MOU	Memorandum of Understanding
MRMC	**(see USAMRMC)**
MTF	**Military Treatment Facility**
NAMRL	**Naval Aerospace Medical Research Lab**
NAMRU	**Naval Medical Research Unit**
NCCOSC	**Navy Center for Combat and Operational Stress Control**
NCRMD	**National Capitol Region Medical Directorate**
NDE	*National Data Extracts*
NDS	*National Data Systems*
NH	**Naval Hospital**
NHB	**Naval Hospital Bremerton**
NHCL	**Naval Hospital Camp LeJeune**
NHCP	**Naval Hospital Camp Pendleton**
NHJax	**Naval Hospital Jacksonville**
NHRC	**Naval Health Research Center**
NIAID	National Institute of Allergy and Infectious Disease
NICoE	**National Intrepid Center of Excellence**
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NMC	**Naval Medical Center**
NMCP	**Naval Medical Center Portsmouth**
NMCSD	**Naval Medical Center San Diego**

NME	**Navy Medicine East**
NMNCA	**Navy Medicine National Capitol Region**
NHP	**Naval Hospital Pensacola**
NMRC	**Naval Medical Research Center**
NMRDC	**Navy Medical Research and Development Command**
NMRU	**Naval Medical Research Unit**
NNMC	**National Naval Medical Center**
NPC	*Nonprofit Corporation*
NPO	**Nonprofit Organization**
NRAC	*National Research Advisory Board*
NRC	National Research Council
NRI	*Nursing Research Initiative*
NRL	**Naval Research Laboratory**
NSF	National Science Foundation
NSMRL	**Naval Submarine Research Lab**
O&M	**Operations & Maintenance**
OASD	**Office of Assistant Secretary of Defense**
OEF	**Operation Enduring Freedom**
OER	Office of Extramural Research
OGC	Office of General Counsel
OGE	Office of Governmental Ethics
OHRP	Office of Human Research Protections (HHS)
OICI	Office of Interagency Collaboration
OIF	**Operation Iraqi Freedom**
OIRA	Office of Information and Regulatory Affairs
OM	**Operational Management**
OMB	Office of Management and Budget
OND	**Operation New Dawn**
ONR	**Office of Naval Research**
ORD	*Office of Research & Development*
ORH	*Office of Rural Health*
ORI	Office of Research Integrity (HHS)
ORISE	**Oak Ridge Institute for Science and Education**
ORO	*Office of Research Oversight*
ORP	**Office of Research Protections**
ORTA	**Office of Research and Technology Applications**
OSD	**Office of the Secretary of Defense**
OSR	**Office of Scientific Research**
OTT	**Office of Technology Transit**
OUSD	**Office of the Undersecretary of Defense**
P&R	**Personnel & Readiness**
P6	**Program 6 funds (RDT&E)**
P8	**Program 8 funds (Clinical O& M)**
PALT	*Procurement Action Lead Time*
PA	Program Announcement
PAO	Public Affairs Office
PAS	Privacy Act Statement
PD	Project Director
PH	Psychological Health
PHI	Protected Health Information
PHRP	Partnership for Human Research Protection
PI	Principal Investigator
PIA	Privacy Impact Statement
PII	Personally Identifiable Information
P.L.	Public Law
POC	Point of Contact
PRA	Paperwork Reduction Act
PRC	*Polytrauma Rehabilitation Center*
PRIDE	*Program for Research Integrity, Development and Education*
PT/BRI	Polytrauma and Blast-Related Injury
PTSD	Posttraumatic Stress Disorder
QA	Quality Assurance
QUERI	*Quality Enhancement Research Initiative*
QI	Quality Improvement
R&D	Research & Development
R&R OPI	Research & Related Other Project Information
RA	Research Assistant
RACO	*Research Assurance & Compliance Officer (VISN level)*
RAD	**Research Area Directorate**
RCO	*Research Compliance Officer (Facility level)*
RCR	Responsible Conduct of Research
RCS	Report Control Symbol
RDECOM	**Research Development and Engineering Command**
RDIS	*Research & Development Information System*
RDT&E	**Research, Development, Testing & Evaluation**
REAP	*Research Enhancement Award Programs*
RFI/RFP	Request for Information/Requests for Proposal
RIO	Research Integrity Officer
RISC	Regulatory Information Service Center
RMC	**Regional Medical Center**
RNIHS	Research Not Involving Human Subjects
ROCIS	**RISC and OIRA Consolidated Information System**
RR&D	*Rehabilitation Research & Development*
RRP	*Rapid Response Projects*
S&T	**Science and Technology**
SAMMC	San Antonio Military Medical Center

Appendix A

SAQ	System Assurance Questionnaire
SAS	*Statistical Analysis System*
SCI	Spinal Cord Injury
SDR	*Service Directed Research*
SecDef	Secretary of Defense
SES	Senior Executive Service
SMRB	Scientific Merit Review Board
SOP	Standard Operating Procedure
SORN	**System of Records Notice**
SOTA	State of the Art
SOW	Statement of Work
SPM	*Scientific Program Manager*
SPORE	Specialized Programs of Research Excellence
SRS	*Subcommittee on Research Safety*
SSN	Social Security Number
SSV	**System Security Verification**
STARRS	**Study to Assess Risk and Resiliency in Servicemembers**
T2	**Technology Transfer**
TAM	**Thrust Area Manager**
TAMC	**Tripler Army Medical Center**
TATRC	**Telemedicine & Advanced Technology Research Center**
TBI	Traumatic Brain Injury
TEAM	Telemedicine-Enhanced Antidepressant Management
TIN	Tax Identification Number
TMA	**TRICARE Management Activity**
TMA	*Talent Management System*
TRL	**Technology Readiness Level**
TSNRP	**TriService Nursing Research Program**
TTP	*Technology Transfer Program*
UCFR	**Unit Commander's Finance Report**
USAARL	**US Army Aeromedical Research Laboratory**
USACEHR	**US Army Center for Environmental Health Research**
USADTRD	**US Army Dental and Trauma Research Detachment**
USAF	**US Air Force**
USAFSAM	**US Air Force School of Aerospace Medicine**
USAISR	**US Army Institute of Surgical Research**
USAMMA	**US Army Medical Materiel Agency**
USAMMDA	**US Army Medical Materiel Development Activity**
USAMRAA	**US Army Medical Research Acquisition Activity**
USAMRICD	**US Army Research Institute of Chemical Defense**
USAMRIID	**US Army Research Institute of Infectious Diseases**
USAMRMC	**US Army Medical Research and Materiel Command**
USAMRU-K	**US Army Research Unit - Kenya**
USAMRU-E	**US Army Research Unit - Europe**
USARIEM	**US Army Research Institute of Environmental Medicine**
USC	**US Code**
USN	**US Navy**
USU/USUHS	**Uniformed Services University of the Health Sciences**
VA	*Veterans Affairs (see DVA)*
VACO	*VA Central Office*
VAMC	*VA Medical Center*
VAPI	*VA Protected Information*
VCE	DOD Vision Center of Excellence
VLER	Virtual Lifetime Electronic Record
VHA	*Veterans Health Administration*
VINCI	*VA Informatics and Computing Infrastructure*
VIReC	*VA Information Resource Center*
VISN	*Veterans Integrated Service Network*
VistA	*Veterans Health Information Systems and Technology Architecture*
VPN	Virtual Private Network
VRGET	Virtual Reality Graded Exposure Therapy
VSSC	*VHS Support Service Center*
WOC	*Without Compensation*
WHS ESD	**Washington Headquarter Services Executive Services Directorate**
WII	**Wounded, Ill, and Injured Program**
WPAFB	**Wright-Patterson Air Force Base**
WRAIR	**Walter Reed Army Institute of Research**
WRIISC	**War Related Illness and Injury Study Center**
WRNMMC	**Walter Reed National Military Medical Center**

The following resources offer additional assistance:

VA Acronyms List:
www.va.gov/osdbu/library/acronyms.asp

VA Office of Research Oversight "Commonly Used Definitions in VA and VA Research Communities":
www.va.gov/ORO/Acronyms.asp

DoD Dictionary of Military and Associated Terms:
www.dtic.mil/doctrine/new_pubs/jp1_02.pdf

Templates/Sample Documents

VA Templates

VA Research Funding editable forms are available on the VA Intranet R&D website:
www.research.va.gov/funding/process/forms.cfm

DoD Templates

Personally Identifiable Information (PII), Protected Health Information (PHI), and/or Limited Data Set (LDS) Data Use Agreement (DUA): Submit if your project requires access to or extraction of PII or PHI data (encrypted or not) from systems that are owned or managed by TRICARE Management Activity (TMA).
www.tricare.mil/tma/privacy/downloads/2010630/TMA Data Use Agreement Template for PII-PHI-LDS Data Rev 6-30-2010.doc

Instructions for Completing PII, PHI or LDS DSA
www.tricare.mil/tma/privacy/downloads/2010630/DUA Instructions Final Rev 6-24-2010.doc

De-Identified (DIF) DUA: Submit if your project requires access to or extraction of MHS data that have been de-identified in accordance with subparagraph C8.1.3 of DoD 6025.18-R.
www.dtic.mil/whs/directives/corres/pdf/602518r.pdf

DUA: Submit when requesting a DUA that involves subcontractor project support.

System Security Verification (SSV) (formerly System Assurance Questionnaire [SAQ]): Submit when PHI obtained through a DSA will be placed on a system that has not been granted a DoD Authorization to Operate (ATO) or an Interim Authorization to Operate (IATO).
www.tricare.mil/tma/privacy/downloads/FINAL_APPROVED_SSV_Locked.doc

Change in DSA Sponsor: Submit to change the Sponsor on an existing DSA.
www.tricare.mil/tma/privacy/downloads/Change_of_Government_Sponsor_1.14.13.pdf

Change in DSA Custodian: Submit to change the Custodian on an existing DSA.
www.tricare.mil/tma/privacy/downloads/2010630/DUA Change in Custodian Template.doc

DSA Modification Request: Submit to modify an existing DSA.
www.tricare.mil/tma/privacy/downloads/Modification_Request_1.14.13.pdf

DSA Extension Request: Submit to request a 30-day extension on an existing DSA.
www.tricare.mil/tma/privacy/downloads/Extension_Request_1.14.13.pdf

DSA Renewal Request: Submit to renew an existing DSA.
www.tricare.mil/tma/privacy/downloads/Renewal_Request_4.2.13.pdf

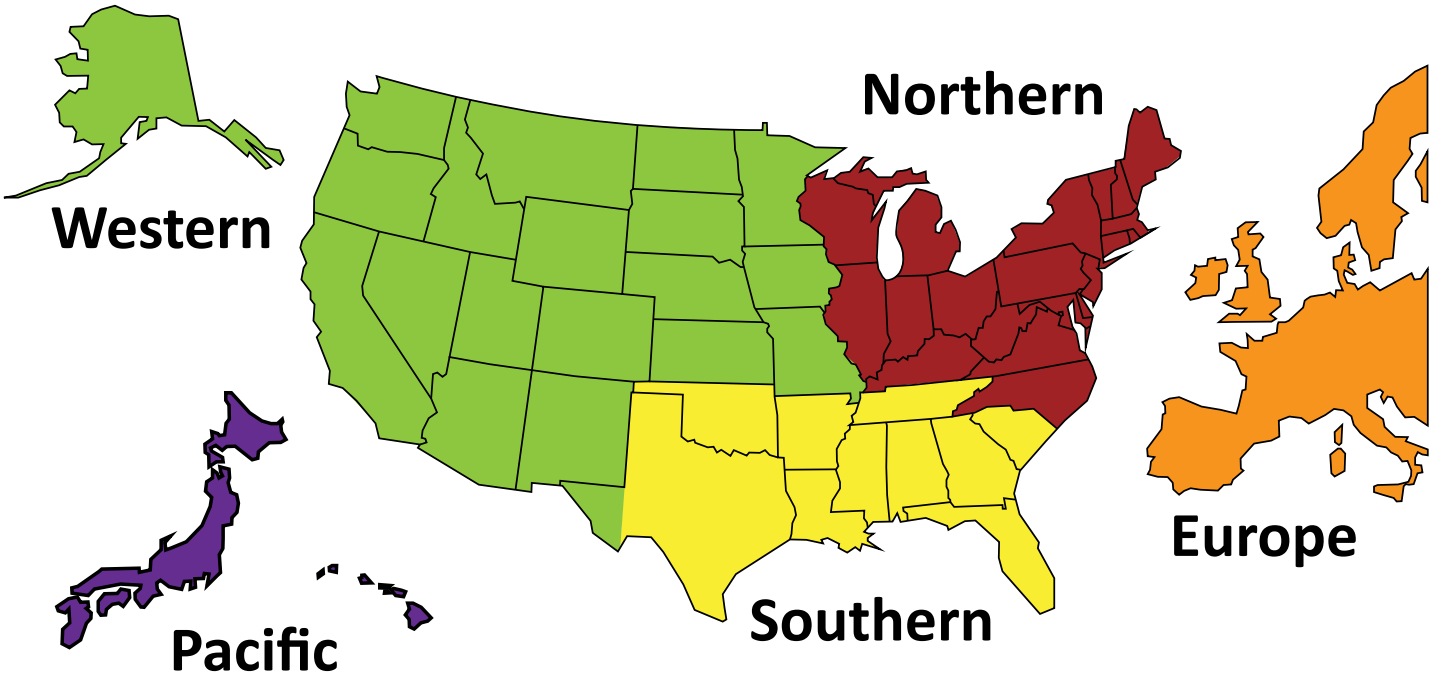
Certification of Data Destruction: Required when your DUA expires, unless you are requesting a renewal. The CDD must be received by the TMA Privacy Office within 30 days following the completion of a project or the expiration of a DSA.
www.tricare.mil/tma/privacy/downloads/20100204/Certification of Data Destruction.doc

Appendix C

VA-Affiliated Nonprofit Corporation Locations

This map can be found online at www.navref.org.

D. The Army Clinical Investigation Program (CIP) by Region



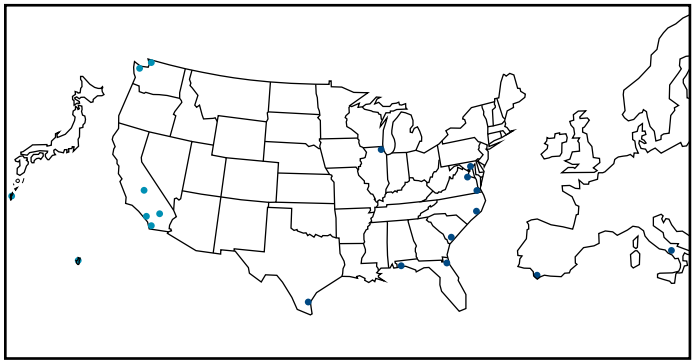
Europe Region (ERMC)	
Landstuhl RMC, GR	ERMC uses BAMC IRB;, is converting to IRBO
Bavaria Medical Dept. Act, GR	
Europe RMC, Heidelberg, GR	
Northern Region (NRMC)	
(IRB) Walter Reed National Military Medical Center, Washington, DC www.wrnmmc.capmed.mil	WRNMMC, WAMC, and KACH have IRBs MRMC is not part of the CIP
DeWitt Army Community Hospital, Fort Belvoir, VA www.fbch.capmed.mil	
Kimbrough Ambulatory Care Center, Fort Meade, MD kacc.narmc.amedd.army.mil	
(IRB) Womack Army Medical Center, Fort Bragg, NC www.wamc.amedd.army.mil	
(IRB) Keller Army Community Hospital, West Point, NY kach.amedd.army.mil	
Northern RMC (P), Fort Belvoir, VA www.narmc.amedd.army.mil	
Ireland Army Community Hospital, Fort Knox, KY www.iach.knox.amedd.army.mil	
Guthrie Medical Department Activity, Fort Drum, NY www.drum.amedd.army.mil	
Kenner Army Health Clinic, Fort Lee, VA kenner.narmc.amedd.army.mil	
McDonald Army Community Hospital, Fort Eustis, VA mcdonald.narmc.amedd.army.mil	

(continued on next page)

The Army Clinical Investigation Program (CIP) by Region (continued)	
Southern Region (SRMC)	
(IRB) Brooke Army Medical Center, Fort Sam Houston, TX sammc.amedd.army.mil	BAMC and DDEAMC have IRBs
Carl R. Darnall Army Medical Center, Fort Hood, TX www.crdamc.amedd.army.mil	
Reynolds Army Community Hospital, Fort Sill, OK www.rach.sill.amedd.army.mil	
Bayne-Jones Army Community Hospital, Fort Polk, LA www.polk.amedd.army.mil	
(IRB) Dwight D. Eisenhower AMC, Fort Gordon, GA www.ddeamc.amedd.army.mil	
Blanchfield Army Community Hospital, Fort Campbell, KY www.campbell.amedd.army.mil	
Fox Army Health Center, Redstone Arsenal, AL www.redstone.amedd.army.mil	
Lyster Army Health Clinic, Fort Rucker, AL www.rucker.amedd.army.mil	
Martin Army Community Hospital, Fort Benning, GA www.martin.amedd.army.mil	
Moncrief Army Community Hospital, Fort Jackson, SC www.moncrief.amedd.army.mil	
Winn Army Community Hospital, Fort Stewart, GA www.winn.amedd.army.mil	
Western Region (WRMC)	
(RMC) (IRB) Madigan Army Medical Center, Fort Lewis, WA www.mamc.amedd.army.mil	MAMC and WBAMC have IRBs
Evans Army Community Hospital, Fort Carson, CO evans.amedd.army.mil	
Bassett Army Community Hospital, Fort Wainwright, AK www.afhcp.org/bassett-army-community-hospital	
Weed Army Community Hospital, Fort Irwin, CA www.irwin.amedd.army.mil	
(IRB) William Beaumont Army Medical Center, Fort Bliss, TX www.wbamc.amedd.army.mil	
Bliss Army Health Center, Fort Huachuca, AZ rwbach.huachuca.amedd.army.mil	
General Leonard Wood Army Community Hospital, Fort Leonard Wood, MO glwach.amedd.army.mil	
Irwin Army Community Hospital, Fort Riley, KS iach.amedd.army.mil	
Munson Army Health Center, Fort Leavenworth, KS www.munson.amedd.army.mil	
Pacific Region (PRMC)	
Camp Zama, Japan	TAMC is IRB for 18th MEDCOM
Tripler Army Medical Center (TAMC), Honolulu, HI www.tamc.amedd.army.mil	
Korea	

E. The Navy Clinical Investigation Program (CIP) by Region

Navy Medicine West
NMC San Diego
- NH Bremerton
- NH Lemoore
- NH Oak Harbor
- NH Okinawa
- NH Guam
- NH Pendleton
- NH 29 Palms



Navy Medicine East
NMC Portsmouth
- NH Beaufort
- NH Corpus Christi
- NH Camp Lejeune
- NH Jacksonville
- NH Naples
- NH Rota
- NH Pensacola
- NHCL Annapolis
- NHCL Great Lakes
- NHCL Quantico

Navy Medicine East	
NMC Portsmouth www.med.navy.mil/sites/nmcp	IRB at NMC Portsmouth
NH Camp Lejeune www.med.navy.mil/sites/nhcl	
NH Jacksonville www.med.navy.mil/sites/navalhospitaljax	
NH Pensacola www.med.navy.mil/sites/pcola	
NH Corpus Christi www.med.navy.mil/sites/nhccc	
NH Beaufort www.med.navy.mil/sites/nhbeaufort	
Naval Operational Medicine Institute www.med.navy.mil/sites/nmotc	
NH Rota www.med.navy.mil/sites/nhrota	
EMF Kuwait	
NH Naples www.med.navy.mil/sites/napoli	
NHCL Annapolis www.med.navy.mil/sites/annapolis	
NHCL Quantico www.med.navy.mil/sites/nhcq	

(continued on next page)

Appendix E

The Navy Clinical Investigation Program (CIP) by Region (continued)

Navy Medicine West	
NMC San Diego www.med.navy.mil/sites/nmcsd	IRB at NMC San Diego
NH Bremerton www.med.navy.mil/sites/nhbrem	
NH Pendleton cpen.med.navy.mil	
NH Oak Harbor www.med.navy.mil/sites/nhoh	
NH 29 Palms www.med.navy.mil/sites/nhtp	
NH Lemoore www.med.navy.mil/sites/nhlem	
NHCL Hawaii www.med.navy.mil/sites/nhch	
NH Okinawa www.med.navy.mil/sites/nhoki	
NH Yokosuka www.med.navy.mil/sites/nhyoko	
NH Guam www.med.navy.mil/sites/usnhguam	

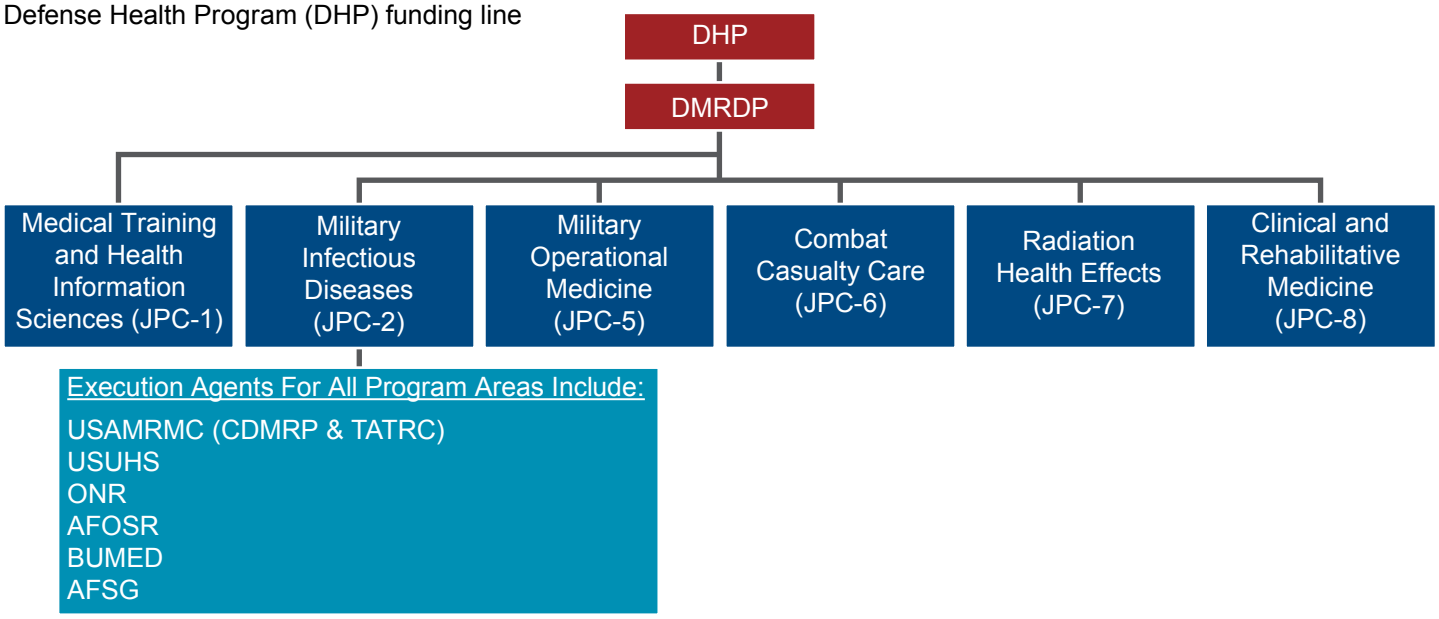
VA/DoD Collaboration Checklist for Investigators

	Proposal Preparation/Project Planning Phase
	1. Identify collaborator(s) at participating institutions
	2. Develop proposal idea (with specific aims that identify a significant problem of importance to VA/DoD)
	3. Meet with potential collaborators (in person, if possible) to discuss project details
	4. Contact research administration (including IRB) at each agency to discuss project plans
	5. Submit a Letter of Intent (LOI) if necessary
	6. Develop your proposal: request input/review of your proposal from coinvestigators and collaborators
	7. Develop a project timeline, taking into consideration the relevant approvals required
	8. Develop budget
	9. Meet with administrative personnel at both agencies to confirm plans for research administration (space, hiring plans, equipment, supplies, other budget needs, etc.)
	10. Submit proposal
	Preparation for Research Activities Following Award Notification (Note: Many of these items are done in parallel, not sequentially)
	1. Meet with study investigators at involved sites.
	2. Submit the protocol to all applicable approval authorities (e.g., IRB, safety, information collections at each participating site)
	3. Finalize and sign all agreements (e.g., CRADA, MOU/MOA, contract, IPA, IAIR, DSA)
	4. Begin contracting and hiring procedures
	5. Train project staff and develop project standard operating procedures for research integrity, data sharing, and media and public relations
	6. Initiate and conduct research project

Appendix G

DHP Funding Line and List of Joint Program Committees (JPCs)

Defense Health Program (DHP) funding line



Army Engaged Personnel and Institutions Table (Sample)

SUBJECT: Proposal, "Title," Submitted by Investigator, Ph.D., Institution, HI, Awardee: Institution, Honolulu, HI, Proposal Log Number XXXXX, Award Number XXXXX-XXX-XXX, HRPO Log Number A-XXXXX.

PERSONNEL	INSTITUTION	ROLE
	Institution 1	Awardee
Dr. S	Institution 2	PI
Dr. R	Institution 3	Associate-I
COL L	Institution 3	Associate-I
Dr. M	Institution 3	Associate-I
LCDR W	Institution 4	Associate-I, Research Site Investigator
Dr. A MD	Institution 5	Consultant
Dr. A, Ph.D.	Institution 6	Consultant