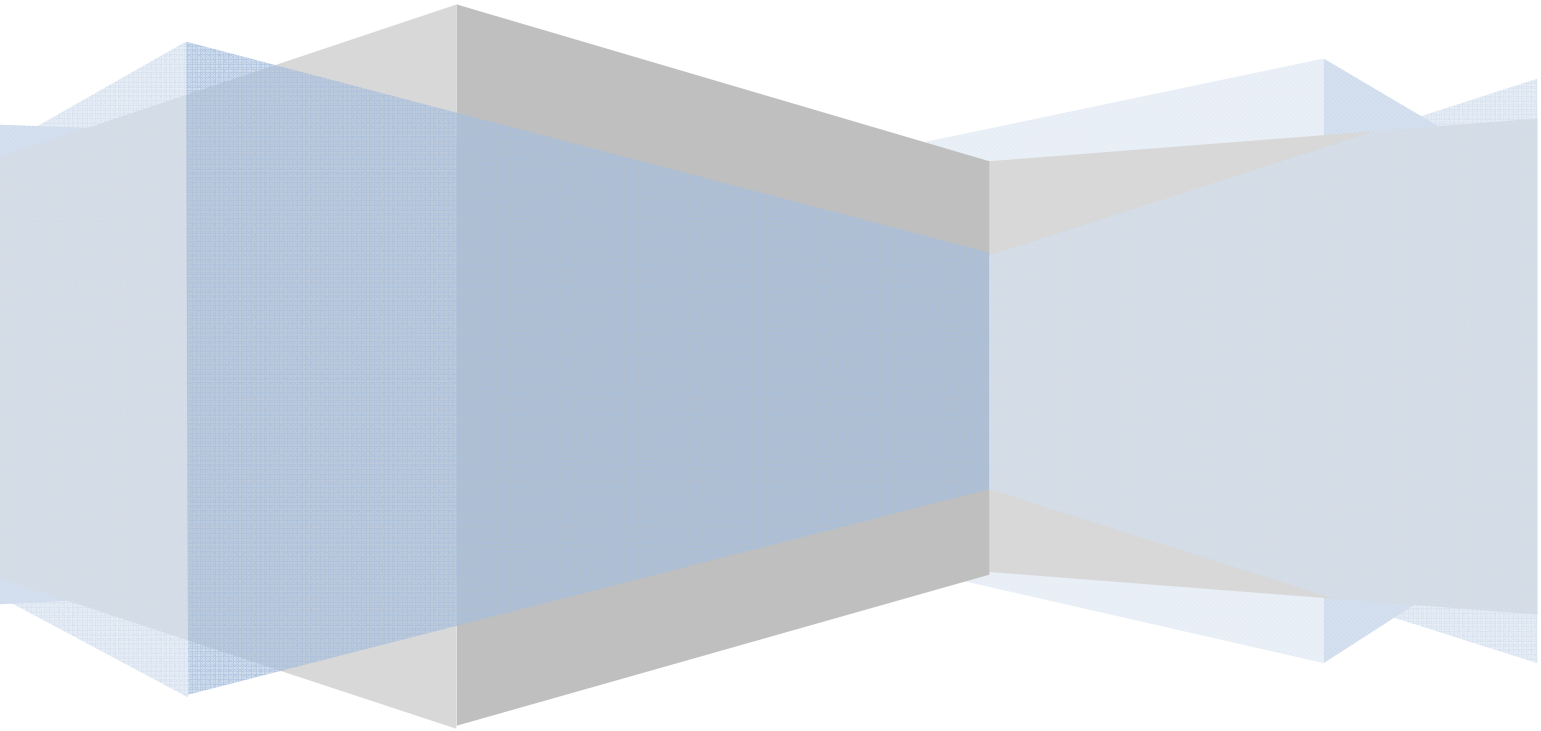
VA/DoD Collaboration Guidebook for Healthcare Research



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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 Department of the Army or the Department of Defense.

To the best of our knowledge, the information in this Guidebook is current as of January 24, 2011.

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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). This 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 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 and unsuccessful research collaborations, a list of commonly used acronyms, and links to additional resources. We provide tips from experienced researchers on how to maximize available resources and make recommendations for future consideration. We hope readers of this Guidebook will find it valuable in collaborative research efforts for the continuing benefit of our service members, Veterans, and both healthcare systems.

Intended Audience:
VA and DoD healthcare human subject researchers, clinicians, research administrators
Suggested Uses:
Planning for initiation & administration of collaborative research efforts

a. VA/DoD Collaborations

Over the past 20 years, there have been numerous legislative efforts to encourage and increase collaboration between the VA and DoD, covering issues from the construction of military and VA healthcare facilities[1] to the sharing of electronic medical records. Collaboration, working together for a common goal, is one of three guiding principles of the VA/DoD Joint Strategic Plan for 2009 - 2011: *to achieve shared goals through mutual support of both our common and unique mission requirements*.[2]

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 FY2010, there were 274 direct sharing agreements between 100 VA medical centers (VAMCs) and 124 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 human subject healthcare researchers and clinicians working in the VA and the DoD. 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.

[1] Pub. L. 108–375, div. B, title XXVIII, § 2811, Oct. 28, 2004, 118 Stat. 2128
[2] http://www.tricare.mil/DVPCO/downloads/SIGNED%20JSP%20FY09-11%2001-08-2009%20FINAL.pdf

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. When planning a collaborative effort, it's important to match researchers with common interests to explore important questions.

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 the Department of Veterans Affairs.

Figure 1. Reasons to Collaborate

a. Research Collaboration

Research partnerships take many forms and involve various personnel depending on the scope of the project. Research and clinical partnerships occur when a collaboration develops between individuals or teams from both Departments, each with knowledge of and experience with the people, priorities, and practices of their Department. There are both civilian and military researchers within the DoD and the 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 and is in line with departmental and facility policies, priorities, and practices. Researcher involvement is equally crucial to make certain that the study has sound scientific design, ensures human subjects are protected, utilizes appropriate analytical methods, and is disseminated into the scientific literature.

While such collaborative efforts may present unique challenges, such as credentialing and guiding collaborators with less research experience through the process, this partnership of perspectives and skill sets can also increase the likelihood of success and translation into the field.

b. Overview of Research Personnel

Investigators need to consider differences in how the Departments fund research prior to the initiation of a collaborative effort. Salary support for VA researchers is outlined in Table 1 and for DoD researchers in Table 2.

VA Research Personnel

Most physician researchers within the VA are similar to DoD clinician researchers in that their salaries are paid by clinical care dollars and cannot be paid by research funds. The VA employs research scientists and career scientists whose salaries are supported by research dollars for specific time periods. The VA has academic affiliates that, in some instances, may supplement a researcher's income and provide tenure and academic title. The VA also allows affiliated staff to become without compensation (WOC) employees, which grants limited VA privileges without receiving direct compensation from the VA.

Table 1. 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 (Nonphysician) Researcher	Clinical care dollars or research dollars

DoD Research Personnel

DoD funding sources are often categorized by the "color of money," referring to either Program 6 (P6), which are research, development, testing, and evaluation (RDT&E) dollars, or Program 8 (P8), which are clinical dollars. 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 (P6 dollars). 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 military treatment facilities (MTFs) or research laboratories but cannot provide clinical care. Fellows and interns can provide research assistance appropriate to their educational program and allowed by their graduate medical education (GME) program training director.

DoD researchers may have scientific academic affiliations with the Uniformed Services University of the Health Sciences (USU/USUHS). DoD research centers may have researchers who are salaried, tenured through the USU, or on "soft money" (grant-funded, usually supported by foundations).

Table 2. DoD Research Personnel and Funding Sources

DoD RESEARCH POSITIONS	MILITARY PERSONNEL	CIVILIAN PERSONNEL	
	Active Duty Military	Research Dollars (P6)	Clinical Dollars (P8)
Clinician Involved in Research			
Clinician in Military Treatment Facilities (MTFs)	X		X
Clinician in Department of Clinical Investigations	X	X(Navy only)	X
Clinician in research laboratories	X	X	X(Navy only)
Contract staff		X(Navy only)	X
Dedicated Research Staff			
Personnel in research laboratories	X	X	X(Navy only)
Contractor/Intergovernmental Personnel Act (IPA)		X	X(Navy only)
Academic Affiliation			
Faculty position at military institution (i.e. USUHS, service academies, etc.)	X		X
Student/intern/fellow in military education program	X		X
Faculty/student in civilian academic institution	X(Navy only)	X	

c. Benefits and Challenges

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

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

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 clinical, research 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.
- Access to medical records and protected health information is limited to research and/or clinical staff within each agency. There are barriers to data sharing yet to be overcome.

- Access to and availability of necessary facilities, including laboratory and office space, and information technology support may be limited.

These challenges can be mitigated through careful planning and coordination, as discussed later in this Guidebook.

3. Identifying Ongoing Research Efforts

Before research collaboration is initiated, it is helpful to identify other related research that has been conducted or is currently underway. A literature search to identify previously published work is a natural place to start. PubMed search terms can be used to identify research conducted by DoD or VA researchers or at DoD or VA sites. It is more challenging to locate ongoing studies and identify potential collaborators, even though, at any given time, there are numerous ongoing research projects at both the VA and DoD. Some suggested resources to search or contact are included in Tables 3 and 4. There are also new and developing VA/DoD Joint Centers of Excellence (COEs) including Centers for Psychological Health and Traumatic Brain Injury, Vision, Hearing, Battlefield Health and Trauma Research, Orthopaedic Trauma and Amputees.

Table 3. General and VA Research Resources

WEBSITE OR SOURCE	DESCRIPTION
General Sources for Clinical Trials	
www.ClinicalTrials.gov	A registry of federally and privately supported clinical trials conducted in the United States and around the world
www.centerwatch.com	A registry of clinical trials available for search, along with training information
http://fhp.osd.mil/deploymed	Provides information on DoD and other federally funded research on deployment-related issues
VA Research Sources	
www.hsrd.research.va.gov/research	Within the VA, all Health Services Research & Development (HSR&D)-funded projects can be found on this website, sorted by project status (i.e. newly funded, current, completed), designated research area (DRA), designated research elements (DRE), portfolio (i.e. mental health, long-term care) and research center
RDIS database	Also known as ePromise; the Research and Development Information System (RDIS) is a VA database of all researchers and research projects. You may need to contact your local VA Administrative Officer to access this database
http://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 can access the ART website and database, as users must be logged into the VA network to access the ART website
http://vaww.research.va.gov/resources/pubs (VA Intranet)	This site makes VA Annual Reports from 1997-2003 available and may be another source of 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 Facility (MTF) Centers	Talk with multiple personnel at a variety of MTF sites, such as the Defense and Veterans Brain Injury Center (DVBIC) and the National Intrepid Center of Excellence (NICoE), as there may be different strategies identified from different people at different sites
http://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 the VA.

Table 4. DoD Research Resources

WEBSITE OR SOURCE	DESCRIPTION
DoD Research Sources	
http://www.dtic.mil/dtic/search/tr/index.html	The Defense Technical Information Center (DTIC) site has links for research funded through the DoD.
http://cdmrp.army.mil	DoD's Congressionally Directed Medical Research Programs (CDMRP) website
http://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.
http://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.
http://www.darpa.mil/index.html	The Defense Advanced Research Projects Agency (DARPA) funds unique and innovative research through the private sector, academic and other nonprofit organizations as well as government labs.
Army Research Sources	
http://www.arl.army.mil/www/default.htm	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.
https://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 Sources	
http://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.
http://www.med.navy.mil/sites/nmrc/Pages/index.htm	The Naval Medical Research Center (NMRC) is the Navy's lead medical research and development laboratory. The NMRC and its eight subordinate laboratories around the world enhance the health, safety, readiness, and performance of Navy and Marine Corps personnel through basic and applied biomedical research.
http://www.med.navy.mil/sites/nhrc/Pages/Research.aspx	The Naval Health Research Center (NHRC) serves as a research and development laboratory for the DoD.
Air Force Research Sources	
http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=8981	The Air Force Office of Scientific Research (AFOSR) manages the basic research investment for the U.S. Air Force.

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Section II. The Nuts and Bolts

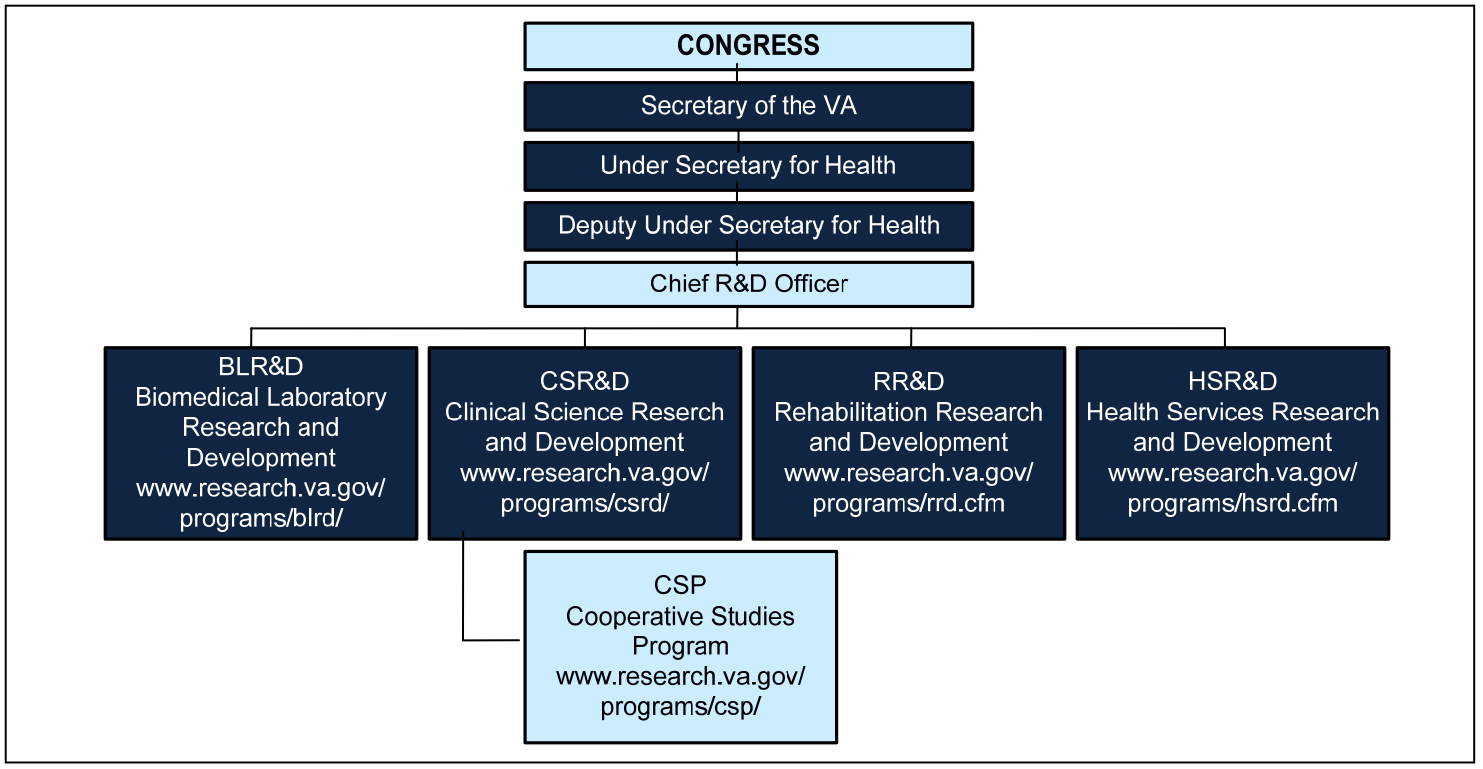
1. Guide to Research Infrastructure

a. VA Research Infrastructure

VA Office of Research and Development (ORD)

The ORD is comprised of four services under the direction of the Chief Research and Development Officer (CRADO). The R&D program is an intramural program spanning the continuum from basic biomedical research through to translation of research into practice, emphasizing the health concerns of Veterans. Descriptions of each of the VA research services and 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 R&D Services

VA research is conducted at most of the 153 parent VA medical centers (VAMCs) and almost 1,000 community-based outpatient clinics (CBOCs), at VA-sponsored events, at affiliated academic institutions, and in local communities.

Many larger VAMCs have their own R&D program to administer intramural research funds, assist staff in the development of all research activities, and oversee the R&D Committee. At facilities with large programs, the Associate Chief of Staff/Research (ACOS/R) is responsible for the day-to-day management of the research program and the Administrative Officer (AO) is responsible for the administrative functions of the research program. Staffing levels and local R&D policies 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. Research leadership for local VAMCs is found at: http://www.research.va.gov/about/national_directory.cfm

VA-Affiliated Nonprofit Corporations (NPCs)

Most non-VA research (extramural) funds, including funds from other federal agencies, are administered through VA-affiliated NPCs which are present at many, but not all, VAMCs. VA-approved research funds are from non-VA federal agencies, private sector companies, charitable foundations, professional societies, other nonprofit entities, individuals, state and local governments, and universities. More information is available at: http://www.navref.org/index.htm. The best way to locate the associated NPC is to ask the local VA R&D office. In some instances, extramural funds may be administered through an affiliated academic institution.

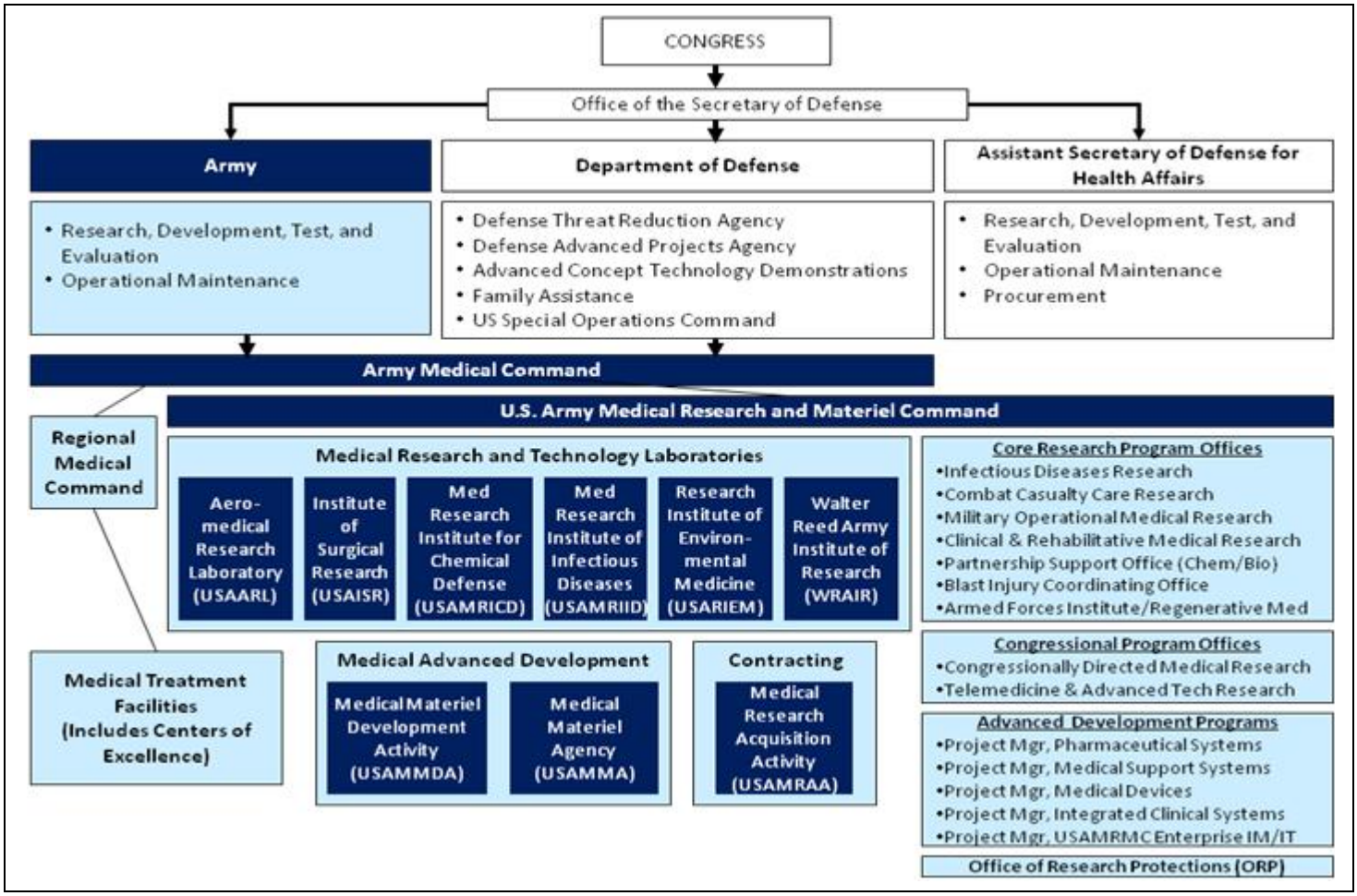
b. DoD Research Infrastructure

The DoD is governed by the Secretary of Defense, with separate branches for the Departments of the Army, Navy, and Air Force. Each Department has their own research infrastructure, as outlined in Figures 3-5. DoD healthcare research efforts 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, nonmilitary hospitals, and at the VA.

Army R&D

Within Army Medical Command (MEDCOM) facilities, research is conducted at the MTFs and the Medical Research and Materiel Command (MRMC) laboratories. A region map and list of Army MTFs is found in Section III.3. Figure 3 shows the organization of Army-managed R&D infrastructure.

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



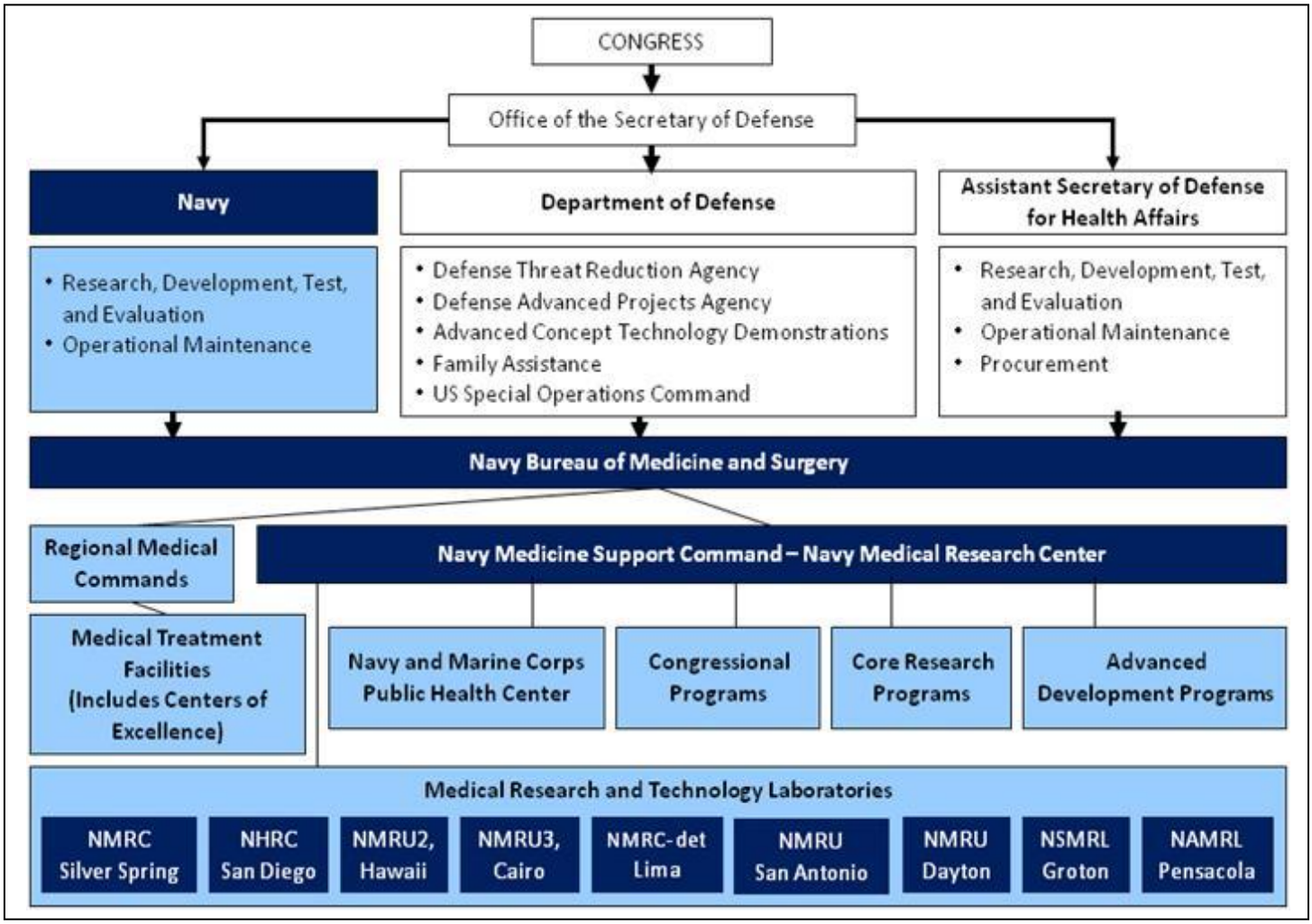
The Army manages both core (President's Budget) and Congressional Special Interest (CSI) funding for medical R&D. Three streams are involved: (1) Army, (2) other DoD programs, and (3) the Assistant Secretary of Defense for Health Affairs (ASDHA). Under the Army, the largest R&D programs are MEDCOM and the ASDHA, which includes the Defense Health Program (DHP). Funding for clinical research is found in two programs: medical R&D (basic research through clinical trials and postmarketing studies) and MTF-sponsored graduate medical education (GME) programs. The MRMC manages both core and CSI funding and programs for medical R&D.

Research, development, testing and evaluation (RDT&E) dollars, also called P6 dollars, may be designated for research efforts at the MTFs or MRMC laboratories and may fund collaborative projects, including with outside agencies and academic colleagues. The Clinical and Rehabilitative Medicine Research Area Directorate (RAD), part of the MRMC, directs and seeks funding for research efforts at the MTFs.

Navy R&D

The Navy Surgeon General, as Chief of the Bureau of Medicine and Surgery (BuMed), is responsible for all medical research within and sponsored by the Navy. The Navy Medical Research and Development Center (NMRDC) is the BuMed-level policy and oversight positional authority for all forms of research and research/analysis-related activities accomplished within or sponsored by Navy Medicine.

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



The NMRDC provides research analysis for issues and projects as assigned and promotes interdisciplinarity and multiculturalism so the Navy Medicine mission evolves into a global systems medicine/systems healthcare community. NMRDC leadership includes positional authority over all research forms and all Operational Medicine, Infectious Diseases, Biodefense, and Bone Marrow regulatory compliance, healthcare delivery alignment, and opportunities development benefiting Navy and Marine Corps 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.

Operational control and execution of research is performed within each of the four Navy Medical Commands (Navy Medicine Support Command and the three regional commands). Navy Medicine Support Command oversees the work performed in the nine Navy Medicine R&D laboratories:

- Naval Medical Research Center (NMRC), Silver Spring, Maryland, is the lead laboratory, with the following scientific directorates: Undersea and Operational Medicine, Infectious Diseases, Biodefense, and Bone Marrow.
- Naval Health Research Center (NHRC), San Diego, California, does medical modeling and simulation (epidemiology), human performance, and respiratory diseases.
- Naval Medical Research Unit (NMRU2), Honolulu, Hawaii, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Unit (NMRU3), Cairo, Egypt, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Center (NMRC) Detachment, Lima, Peru, performs infectious disease surveillance and treatment studies.
- Naval Medical Research Unit (NMRU), San Antonio, Texas, conducts dental research, directed energy effects, and combat casualty care research.
- Naval Medical Research Unit (NMRU), Dayton, Ohio, is the environmental health effects laboratory.
- Naval Submarine Medical Research Laboratory (NSMRL), Groton, Connecticut, conducts health and performance research related to submarine, diving, and surface conditions.
- Naval Aerospace Medical Research Laboratory (NAMRL), Pensacola, Florida, performs research, development, testing, and evaluation in aerospace medicine and related sciences.
- While not a research laboratory, the Navy and Marine Corps Public Health Center provides epidemiologic data, which may be of interest to collaborators.

Research within the Navy MTFs is administrated out of the three Navy Medicine Regional Commands: Navy Medicine West, Navy Medicine East, and Navy Medicine National Capitol Area (see region map and medical center list in Section III.4).

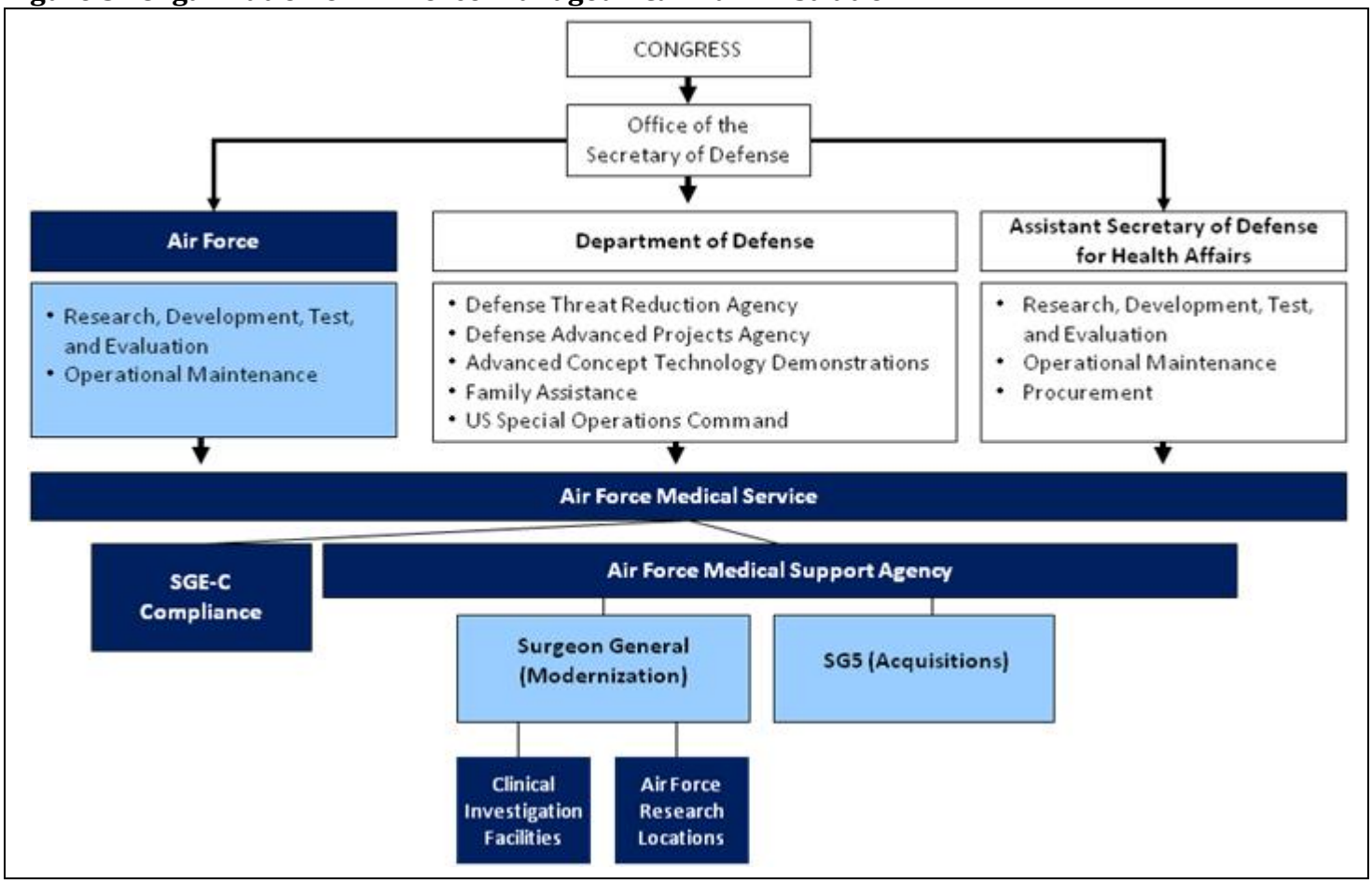
- Naval Medical Center, San Diego, is the MTF laboratory providing administrative and IRB support to the MTF's within Navy Medicine West: Naval Hospital (NH) Camp Pendleton, NH Bremerton, NH 29 Palms, NH Lemoore, NH Guam, NH Okinawa, and NH Yokosuka. The Navy Center for Combat and Operational Stress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

Air Force R&D

The Air Force Surgeon General, Directorate for Modernization (AF/SGR), oversees the Air Force research infrastructure, which is illustrated in Figure 5. For those with a DoD common access card (CAC), the six clinical research facilities and medical research partners are listed and linked at https://kx.afms.mil/clinicalinvestigations

- David Grant Clinical Investigation Facility, Travis Air Force Base, California
- Keesler Clinical Investigation Facility, Keesler Air Force Base, Mississippi
- Wilford Hall Clinical Research Division, Lackland Air Force Base, Texas
- US Air Force Academy Life Science Research Center, Colorado Springs, Colorado
- School of Aerospace Medicine, Wright-Patterson Air Force Base, Ohio
- Wright-Patterson Clinical Investigation Division, Wright-Patterson Air Force Base, Ohio

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



2. Where to Start?

You have a great idea for a research project that involves investigators and/or subjects at both the 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.

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 will 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 occurs between two junior investigators, between a junior and senior, or between two senior investigators. Collaborations may also occur between multiple investigators (or teams) at both Departments. Because collaborative research projects are high risk and 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 with an interest in research but not on a research investigator career trajectory would wish to serve as a site PI. It is likely collaborations between junior investigators will need mentorship from a senior investigator with experience in multi-site and/or interdepartmental collaboration.

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 where you can meet and discuss shared interests and discuss 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 need to reach out to researchers and clinicians through phone calls, emails, and networking. Start by contacting an investigator from your Department who has 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.

***TIP:** Use your professional networks to identify an experienced, knowledgeable, well-connected and trustworthy collaborator who can make the time to devote to project activities.*

- To identify potential VA research collaborators, contact the VA Office of Research and Development and speak to one of the Program Officers in your area. The website http://www.hsrd.research.va.gov/research/portfolio.cfm provides a list of certain topic areas and the responsible scientific program manager (SPM) who you can consult for additional advice. A periodically updated researcher directory that may also be useful to both DoD and VA investigators is available at http://www.hsrd.research.va.gov/for_researchers/directory/.
- To identify Army research collaborators, contact Program Officers at the Telemedicine & Advanced Technology Research Center (TATRC) or Research Area Directorates (RADs). Program Officers are generally aware of research interests and who has funded proposals. The MRMC homepage is also a helpful resource: https://mrmc.amedd.army.mil.
- To identify Navy research collaborators, the Navy Medical Research and Development Center is headed by the special assistant for medical research to the Navy Surgeon General. The Center has policy and oversight

responsibility for all Navy medical research and is located within the Navy Medicine Institute at the Bureau of Medicine and Surgery, Washington, D.C. The center 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 Air Force Surgeon General, Directorate for Modernization, Research and Development Division at: https://kx.afms.mil/s+t, accessible to individuals with a DoD access card. The individuals in this office may be able to direct your protocol towards Air Force interests as well as field collaboration. The Air Force Medical Support Agency (AFMSA) SGEC office can also be a contact for finding an Air Force collaborator. Interested parties can be directed from there to the appropriate Air Force agency.

b. Planning Your Proposal

Once you have identified a potential collaborator, you need to draw up 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).

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

There are many topics to be considered in developing a plan for collaborative research, including funding source, human subjects, scientific methodology, development of collaborative agreements, data sharing, 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.

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 colleague's 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.

TIP: *An experienced VA researcher suggests having a point of contact (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.

c. Crafting and Submitting a Research Proposal

Developing an innovative proposal and a viable collaborative research plan takes significant time and effort. Investigators need to 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.

Optimally, the investigator will have administrative and research support staff to support 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 such agencies as the VA, USU, CDMRP, and TATRC, and it's worth exploring this possibility. Most

successful investigators participating in collaborative projects are situated within departments, facilities, or centers with infrastructure funds to support their planning efforts.

Both the VA and DoD grant submission process involve the use of www.grants.gov. At the VA, all project PIs must be registered with the National Institutes of Health's eRA Commons systems. VA proposal submission due dates for the ORD services are explained in detail on the VA Intranet site: http://vaww.research.va.gov/funding/process/submission-calendar.cfm. Some ORD services require that a letter of intent (LOI) be approved or accepted before investigators can submit a proposal. Other services require the LOI to plan for reviewer assignment.

The DoD's Congressionally Directed Medical Research Program (CDMRP) allows investigators to register and be notified of all CDMRP-managed program announcements at https://cdmrp.org/Register/. Most CDMRP submissions require an LOI to be approved prior to proposal submission. Typically, only a select number of LOIs are invited to submit a full proposal. The website for U.S. Army Medical Research Acquisition Activity (USAMRAA), which is MRMC's contracting element, has links to the Broad Agency Announcements (BAAs), Program Announcements, and Requests for Proposals (RFP) available at http://www.usamraa.army.mil/.

U.S. 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 areas of quality of care, performance enhancement, transition of care, and screening and surveillance. The Clinical Investigations Awards Program provides funding to intramural investigators at the MTFs; however, extramural collaborations are encouraged. While some human subject research projects may be funded, clinical trials are not supported through this office. The U.S. Navy announcements and application procedures can be found at the following website: http://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 https://kx.afms.mil/s+t available to those with CAC access. All DoD extramural research announcements appear on one of two extramural sites for academia and industry: www.fbo.gov or www.grants.gov.

d. Research Integrity

Integrity and trust are fundamental to all aspects of research, from idea generation and proposal writing to the peer review process, conducting the study, and reporting and disseminating 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.

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 constitutes research misconduct. Research misconduct includes the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Research misconduct is a serious offense that may bar an investigator from obtaining future funds. There are VA and DoD mechanisms to address research misconduct.

For the Army, the Department of Health and Human Service Office of Research Integrity Guidebook, Introduction to the Responsible Conduct of Research, is available to all investigators. The Office of Research Protections offers a regular education series through Defense Connect Online (DCO), available at https://www.dco.dod.mil/. 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.

3. Administration of Research Funds

Administration of research funding for collaborative projects takes specialized knowledge and expertise, as policies vary by site and funding (i.e., VA, DoD, National Institutes of Health [NIH], foundation). 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 administrator(s) at proposed site(s) to identify the specific local policies that may impact their project, and work closely with the appropriate research administrator to develop a feasible plan.

a. VA Research Funding

Congressionally appropriated VA R&D funds are allocated by the Veterans Health Administration (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 (defined as having a minimum of 5/8th time VA employment) are funded and able to serve as PIs of VA-funded studies. Investigators from outside agencies and academic institutions can serve as co-investigators or consultants.

Research projects are funded through a variety of peer-reviewed mechanisms, including but not limited to the following:

- investigator initiated research (IIR), also called Merit Reviews
- mentored research (career development)
- large scale, multisite clinical trials (Cooperative Studies Program)
- career scientist
- Quality Enhancement Research Initiative (QUERI)
- pilot funding
- Centers of Excellence (CoEs)
- service-directed projects

Research in the VA is supported by VA research, medical care dollars, funding from other federal agencies, nonprofit corporations (NPCs), and industry. Local VA Research Administration is responsible for the administration of VA intramural funds. If research funds come from non-VA sources, they are administered through the local Veterans Affairs NPC (although Research Administration may be involved in nonfinancial aspects of the project).

b. DoD Research Funding

The 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

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 can act as associate investigators or as research assistants under the direction of the PI.

Table 5. DoD Research Funding Opportunities and Sources

SOURCE OF SUPPORT	TYPE OF AWARD	TYPE OF FUNDS (P6, P8)	WHO CAN SERVE AS PI?
Intramural			
US Army Clinical Investigation Program (CIP) http://fhp.osd.mil/cip.jsp	Intramural funding	P8	Military investigators
US Army Medical Research & Materiel Command https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.overview	Intramural funding to laboratories (i.e. Institute of Surgical Research)	P6	Investigators assigned to military research laboratories
Telemedicine and Advanced Technologies Research Center http://www.tatrc.org/?p=funding_aamti	AMEDD Advanced Medical Technology Initiative funding	P8	Military or General Schedule (GS) investigators at MTF
Navy Commander's grants http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	Local intramural funding	P8	Navy researchers at specific medical centers
Navy Clinical Investigations awards http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	Bureau of Medicine & Surgery (BuMed) intramural funding	P8	Navy researchers at any Navy MTF (collaborations permitted)
Wounded, Ill and Injured Program (WII) http://www.onr.navy.mil/Contracts-Grants/Funding-Opportunities.aspx	BuMed intramural funding	P8	Military investigators (collaborators permitted)
Office of Naval Research (ONR) http://www.onr.navy.mil/	Intramural and extramural	P6	Military, industry, academia in defined program areas
Air Force Clinical Investigation Program http://fhp.osd.mil/cip.jsp	Intramural funding	P8	Military investigators
Air Force Intramural Research http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=8981	Research management working group	P6	Air Force researchers in DoD facilities working on established Air Force thrust areas
Extramural			
Broad Agency Announcement (BAA) http://www.grants.gov	Contracting action	P6	Industry, academia, federal agencies
Program Announcements http://www.grants.gov	Contracting action	P6	Industry, academia, federal agencies
Requests for Proposals (RFP) http://www.grants.gov	Contracting action	P6	Industry, academia, federal agencies
Tri-Service Nursing Research Program (TSNRP) http://www.usuhs.mil/tsnrp/GrantApplications/callforproposals.php	Awards to nonprofit organizations, public university	P8	Military nurses – active duty, Reserve, National Guard, and retired military registered nurses (eligibility criteria vary by type of award)

The DoD funds intramural research efforts through programmed dollars administered by the U.S. Army MRMC: https://mrmc.amedd.army.mil, the U.S. Navy ONR, BuMed: http://www.med.navy.mil/BUMED/Pages/default.aspx, and the U.S. Air Force Surgeon General's Directorate for Modernization: (needs CAC access) https://kx.af.mil/s+t. Additional efforts, both intra- and extramural, are managed by the MRMC through Congressional Special Interests: http://cdmrp.army.mil and www.tatrc.org and allocations through the Defense Health Program. RADs within the U.S. Army MRMC (combat casualty care, military operational medicine, infectious disease, clinical and rehabilitative medicine, and chemical and biological defense) and the ONR Code 34 war-fighter protection 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 medical care dollars. The projects are overseen and approved by the Department of Clinical Investigations 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 P8 clinical dollars, P6 RTD&E funds, or extramural resources via CRADAs (see Section II.4 for more on collaborative agreements). Similarly, Navy medical R&D laboratories may fund a project from any of these sources.

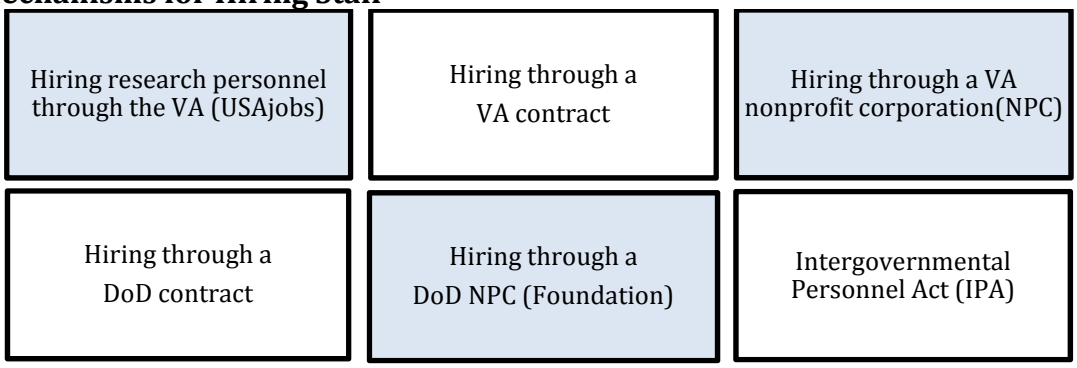
c. Budget Preparation

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 hiring staff (see Figure 6). Administratively, it is simplest if there is already experienced staff at the proposed site that can be dedicated to your project and paid for by research dollars. Unfortunately, this is often not the case, and new staff members need to be recruited and hired. Hiring within the VA and the DoD presents challenges. Researchers have found it very difficult to transfers funds between the VA and the military. Investigators are advised to work closely with an experienced research administrator at each site to assist in the

Figure 6. Mechanisms for Hiring Staff



recruitment and hiring process. Each PI needs to decide whether or not hiring of new personnel will be completed at the lead Principal Investigator'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 variety of mechanisms that can be used to hire project staff are described below.

- Hiring research personnel through the VA (USAJOBS): These positions are considered "Term" and last from one to four years. For more details about term employees, see: http://www.usajobs.gov/EI/temporaryappointments.asp. 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.
- Hiring through a VA contract: An alternative to hiring a federal employee is to hire the employee through a contract. Contracts typically pay for work done on an hourly basis. They can include reimbursement for additional expenses if specified. The time from initiation to signing of a contract can be weeks to months, depending on the workload at your local VA and the complexity of the contract. See Section II.3.d for more contracting information.
- Hiring through a VA NPC: If the project is funded through a non-VA source, you may hire staff either on a contract or as an employee through the nonprofit agency of either the Principal Investigator's site or local VA site. Contracts are usually faster to execute through NPCs than through the VA, as NPCs are not restricted by the same federal contracting policies. Employees of the NPC are typically eligible for full benefits packages. This might be a better option for prospective employees than a contract. Speak with the research administrator at the NPC to find out more about this option.
- Hiring through a DoD contract: Similar to the VA, DoD facilities use contract labor as an alternative to hiring a federal employee. 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) with a vendor to provide labor on an "as required" basis. These often are the most efficient way to obtain labor to support a particular project but often have higher fees than local contracts.
- Hiring through a DoD nonprofit foundation: Not all DoD medical facilities (typically Army) are able to administer research funds directly, thus they usually work with one or more associated nonprofits to procure personnel and supplies. These include agencies such as Henry M. Jackson Foundation for the Advancement of Military Medicine, Geneva Foundation, and Battelle Foundation. If you are a VA investigator with VA funding, you can initiate a contract with a DoD-approved NPC and that organization can hire staff and provide them with a full benefits package.
- 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. These are typically used for higher level personnel (above level GS) who are career or career-conditional federal employees being

TIP: *Both VA and DoD facilities require varying levels of security clearance, credentialing, appointments (i.e. 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.*

used in another agency for inherently governmental actions, not contract employees. An IPA assignment may also be utilized when a research assistant is working at an affiliated university and can be assigned to work on a project at the 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 http://www.opm.gov/programs/ipa/Mobility.asp. There are a number of regulations surrounding the correct use of VA IPA assignments. Please note that the VA and DoD are not able to execute an IPA with each other.

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

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. The VA limits the inclusion of travel in research budgets. Check with local administrators to confirm their policies. Travel arrangements and reimbursement for VA employees can be made through www.fedtraveler.com, a government travel service; however, you will need to speak with your local VA Research Administration and Travel Office to find out if this would work for your study. 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 (i.e., other VAs) or to a DoD site through an affiliated nonprofit organization to allow payment for travel at the local level. 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 research.

Supplies/Equipment

As the study PI, you 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 (i.e., other VAs), or to a DoD site through an affiliated nonprofit organization to allow payment for travel at the local level. 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. In addition, if equipment is shipped to other study sites, a VA Government Property Loan Form (VA Form 0887) must be completed and filed. Read the funding instructions carefully, as there may be restrictions on certain items (i.e., capital equipment).

Consultants

You may also need to hire consultants for your project. This is done using the contracting mechanism. Again, if the qualified consultant is identified in your proposal, it should not be a problem to execute a contract for their work and contribution. Be aware of any annual funding limits for consultant contracts.

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 policies regarding subject compensation. If your subjects are active duty military, they are only permitted to receive compensation under very limited circumstances (e.g., blood draw). There may be exceptions related to participation for those who participate in research during civilian/personal time.

Information Technology (IT)

The VA does *not* allow IT expenses to be included in the budgets for most grant submissions. Standard 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 Associate Chief of Staff/Research (ACOS/R) and Chief Information Officer (CIO) using IT funds made available specifically to support research. Speak with the local VA Administrative Officer to determine whether you are able to apply for IT funds.

The DoD follows similar rules and, in the MTFs, uses P8, BAG4 (budget activity group 4) funds for IT.

Miscellaneous

Each facility has individual fees associated with services, which may include an IRB usage fee, CRADA fee, or other administrative costs. Some VAs allow payment of honorariums for discrete services, such as paying for guests to speak at a conference.

Ultimately, these budgetary decisions depend on the scope of your project and the policies and procedures of your department. 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 the 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 ample 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.

d. 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 bound by federal regulations, and 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 officer(s) who help facilitate timely execution of your contracts. See Figure 7 for more detail on the steps involved in the contracting process.

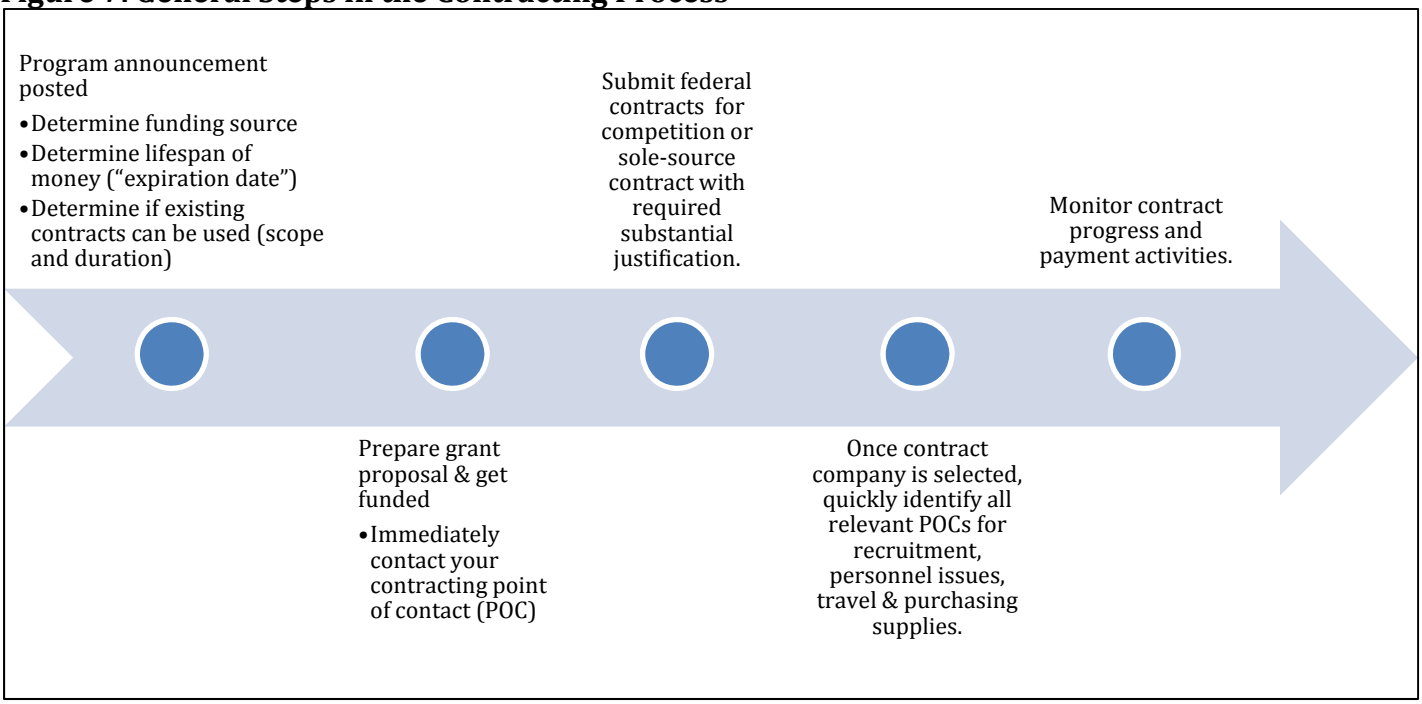
General Contracting Advice

If you have already identified a qualified person with special skills to perform the work, you may be able to write a contract with a sole-source justification. This enables you to secure the contract more quickly instead of sending it out to bid (which is what the government prefers). This will save you a significant amount of time and will give you more control over who is hired for your project. When writing a sole-source justification, it is *very* helpful if this person or institution is named and their qualifications are described in the original grant proposal. Note that if you do sole source the contract, the Justification and Approval (J&A) will be published on the internet at www.fbo.gov (Federal Business Opportunities). Therefore, it is essential that the technical information given be accurate.

It is necessary for investigators or their project management staff to write the statement of work (SOW) for each contract for the local contracting officer. Do *not* give this task to the contracting officer, as they do not know the important details of the study. When writing an SOW, carefully specify the qualifications and technical requirements of the staff to be hired. You must be specific enough to ensure you attract and retain competent personnel, but not so

specific that companies may not compete for the contract due to concerns that they won't be able to find qualified individuals. Specify the responsibilities of staff to be hired (e.g., recruitment, consenting subjects, conducting testing, analyzing data), their duty hours, and expectations for timelines, deliverables, communication, and supervisory oversight. You must also provide objective standards for performance (i.e., data quality, data accuracy). List the individual tasks to be performed under contract.

Figure 7. General Steps in the Contracting Process



If a contract will be put out to bid, requirements should be tailored to ensure that only qualified companies compete. It is allowable to specify that they must have a proven track record in providing, for example, staffing in a specific area. If an unqualified company is awarded the contract, there will be additional hurdles.

Other contracting considerations include:

- Make sure the contract includes wording related to the potential for additional option years (or phases). If additional funding becomes available for that project, it can be added to the end of the contract without having to complete the process again.
- DoD service contracts are for one year and allow only one six-month no-cost extension (18 months total per FAR 52.217-8).
- Indirect costs and fees vary substantially between contract companies. When budgeting, assume a company with high indirect costs will get the award, and be familiar with the cost structure. This ensures there are sufficient salary funds available to hire qualified individuals.
- Clinicians and contracting staff at treatment facilities may not be fully aware of all procedural steps. 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, get updates, and make sure that it stays on the contracting officer's radar screen.
- If it is not in the contract, do not expect to receive it.

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 and if possible.*

Special Considerations for DoD Investigators

MTFs may not be able to accept research funds. Historically, this is one of the most important roles for DoD-affiliated NPCs, as they can receive and disperse research funds. 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 the following:

- What type of money are you receiving: research (P6) or clinical (P8)? This determines the type of work that can be performed.
- When do funds expire? Some funds can only be put on service contracts that have a maximum 18 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 someone you trust from the VA or from an affiliated academic institution. To do this, 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.

4. Formalizing the Collaboration

A critical step in establishing a collaboration is the creation of a formal agreement between research partners that defines the relationship and the expectations of the parties involved. There are a variety of mechanisms available to formalize an agreement, including CRADAs, MOAs/MOUs, and contracts. The types of agencies involved, the requirements of collaborating parties, their relationship and their goals will define the type and structure of the agreement. Overarching agreements like MOUs are handled at the Department level and typically set the stage for collaborative research. Once research is funded, specific agreements must address the scope of work as proposed.

This section suggests general topic areas that should be considered, discussed, negotiated, and agreed upon prior to embarking on a 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. Fortunately, many model agreements are available from the DoD and the VA, and these can serve as a good starting point for developing a customized agreement. Additionally, both Departments have resources at national and local levels to assist investigators in drafting these agreements.

a. VA Collaboration Resources

The local VA Administrative Officer is the first resource to consult about collaborative agreements. The office within the VA that assists investigators in developing collaborative research agreements is the Technology Transfer Program (TTP). The mission of the TTP office 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 non-federal organizations, technology transfer can also occur between federal agencies. Information on the TTP office is available at: www.research.va.gov/programs/tech_transfer/default.cfm.

b. DoD Collaboration Resources

Military collaborators should typically seek advice regarding collaborative research agreements from their local Department of Clinical Investigation (DCI), 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. For example, the DoD Office of Technology Transit monitors all R&D activities that are carried out by or for the military departments and defense agencies and provides access to policies and resources for technology transfer, including model collaborative agreements. Information on the OTT is available at www.acq.osd.mil/ott/.

The Department of Navy (DoN) Technology Transfer (T2) Program 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 Office of Research and Technology Application (ORTA) Manager who can assist in developing and promoting effective partnerships between government and other nonfederal or federal entities. Information on the Navy's T2 Program is available at http://www.onr.navy.mil/Science-Technology/Directorates/Transition/.aspx.

For Navy Medicine, the lead agents are located within the Naval Medical Research Center (NMRC). Each of the regional medical centers and R&D laboratories will have their own ORTA as the local POC to initiate these agreements.

For the Air Force, the Air Force Surgeon General, Directorate for Modernization, Research and Development (AF/SGR) Division is the POC for research-related agreements and facilitating collaborative research.

c. Content of Agreements

Key areas that should be addressed in any formal agreement are shown in Figure 8.

d. Types of Agreements

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 U.S.C. 3710a). These agreements are meant to foster federal/private collaborations to bring new technologies to the public. In some circumstances, CRADAs can be used between two federal agencies (such as the VA and the DoD) and between two federal agencies and a private sector partner. While the CRADA was initially used only for partnering with the private sector, the IRBs of some DoD medical centers now require CRADA use for all collaborative studies. Note that a CRADA cannot provide a mechanism for the direct transfer of study funds between two federal institutions, although it can and should describe the nonmonetary resources (such as personnel, equipment, and space) 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.

Figure 8. Key Content Areas for Research Agreements

Resource Sharing

- A detailed list of all resources being supplied by the partners must be included in any agreement.
- Resources include space, personnel, funds, equipment, and an estimate of in-kind expenses each party is providing for the project and how and where they will be utilized.

Roles and Responsibilities of Each Party

- A list of roles and responsibilities of each party should be specific, and include specific deliverables.

Research Reporting and Publication

- 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

- 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 party may want to protect the IP they bring to the collaborative effort.
- Forms of IP protection include patents, copyrights, trademarks and trade secrets.
- For frequently asked questions about copyright issues affecting the federal government, see: http://www.cendi.gov/publications/04-8copyright.html

Human Subjects Issues

- Human subject concerns should be addressed.
- See Section II.5

Data Use Issues

- Difficulty in D can delay a project's start or even stop a project in its tracks.
- It is critical that potential problems are addressed early on so that you do not waste valuable time later in the project.
- See Section II.6

In addition, the agreement should outline which agency will take the lead in patenting, marketing, and commercialization and how costs associated with these tasks will be allocated.

Table 6 shows some CRADA resources available within the VA.

A CRADA typically contains General Provisions (the legal framework) and an SOW or protocol that provides a detailed explanation of the research to be performed, identifiable phases leading to completion of the research project, deliverables, time estimates for overall project completion, and a budget.

A CRADA can be used to allow 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.

CRADAs can be initiated by federal or industry partners. Some address all provisions in very concrete terms, while others allow for flexibility. The CRADA development and approval process can take as long as six months and

Table 6. VA CRADA Resources

VA CRADA resources are available at:	http://www.research.va.gov/programs/tech_transfer/crada/resources.cfm
For VA investigators: (VA Intranet)	http://vaww.research.va.gov/programs/tech_transfer/crada/va-investigators.cfm
For CRADA collaborators: (VA Intranet)	http://vaww.research.va.gov/programs/tech_transfer/crada
Model CRADAs and other VA agreements are available through:	http://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm

typically involves research administrators and attorneys from each Department.

Within the DoD, CRADA templates may vary across service branches, laboratories, and MTFs. The Air Force and Navy have a standard template, but Air Force CRADAs can vary across organizations and contracting agencies. The Army delegates their CRADA preparation to individual labs. The Clinical Investigations Regulatory Office (CIRO) signs the CRADAs for all the Army medical centers. The majority of these CRADAs are with the collaborating nonprofit research foundations. Army medical centers have umbrella CRADAs with the foundations, so only an SOW is needed for each protocol. The Navy has 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 (e.g., MOAs) are at: http://www.med.navy.mil/sites/nmrc/Pages/ott_ttf.htm. The Air Force will enter into a CRADA when appropriate and can support an existing CRADA from other agencies. For model military CRADAs, see: http://www.acq.osd.mil/ott/techtransit/modelc.htm.

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

MOAs and MOUs are written between parties to define cooperative work together on an agreed-upon project or objective. The MOA/MOU is a binding legal document that holds the parties responsible to their commitment or outlines a partnership. Both the local VA research office and VA Central Office (VACO) execute MOAs/MOUs.

> ***TIP:*** *If you learn that an MOU between the VA and DoD exists that is somehow related to your project or study population, call your project officer to discuss it and its implications.*

5. Human Research Protections

Research involving human subjects that is conducted at both VA and DoD institutions must have complete IRB approval secured at *all participating sites* before any research activities can begin. This requirement may increase usual project start-up time by six months or more. Research activities include subject recruitment, data collection, or chart reviews. Because the 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 is called 45 CFR 46, also known as the common rule. The Food and Drug Administration (FDA) policy is called 21 CFR 50. In addition to following the common rule, both the VA and DoD have additional policies and procedures regarding human subject protections:

- VA: VA protection of human subjects' information is available at 38 CFR 16 and in VHA Handbook 1200.05, available to VA researchers at http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2326 .
- DoD: The Army, Navy, and Air Force have adopted the subparts 45 CFR 46 B, C, and D in their entirety. In addition, DoD services are governed by 10 USC 980 and DoDD 3216.02.
- The Army Human Research Protection Office (AHRPO) also follows 32 CFR 219.
- The DoN Human Research Protections Program (DoN HRPP) follows the common rule 32 CFR 219 and DoN instructions SECNAVINST 3900.39D.

a. VA Research Oversight

The VA Office of Research Oversight advises the 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 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 (PRIDE) is a VA office whose mission is to protect participants in VA human research. PRIDE is responsible for all policy development and guidance and all training and education in human research protection throughout the VA.

VA Levels of Review

The human subject research approval process in the 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. R&D and subcommittee outcomes include the following:

- Approve
- Conditionally approve (require modifications)
- Table (delay a decision)
- Disapprove

All research projects require oversight by a local VA R&D Committee and the appropriate sub-committee, 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 investigators can begin the research. The authority and responsibilities of the R&D and its subcommittees are detailed in VA Handbook 1200.01.

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 full review and approval by the IRB. If an investigator believes his or her human subjects research activity is exempt from review, a request for exemption must be submitted to the IRB.
- *Expedited:* An expedited review procedure consists of a review of research involving human subjects 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 38 CFR 16.110.
- *Full Review*: A full review procedure consists of a full review of the protocol by the IRB.

TIP: *Allow sufficient time to obtain approvals. Most IRB, R&D and other subcommittees meet only once a month, and each VAMC has internal timelines. Because the R&D Committee can't approve the protocol in full 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.

Multisite Collaboration Approval

The VA Central IRB (CIRB) was established to review Office of Research and Development (ORD)-funded multisite human research projects by performing reviews on behalf of all involved IRBs. All VA multisite studies that include ORD funding *must* use the CIRB review/approval process. VA multisite studies that have no ORD funding are *not* eligible to use the CIRB. The VA CIRB meets monthly in person in Washington, D.C., and/or by video or teleconference.

Once the ORD determines that a project will be reviewed by the VA CIRB, the application process is initiated. First, the PI submits an application to the CIRB through their local R&D service. Once the CIRB approves the application or requires only minor modifications for approval, a determination letter is sent to the PI, and a copy of

the application package is sent to all VA facilities listed as potential participating sites. The sites will have 30 days to provide comments to the CIRB. Upon approval of the application, Local Site Investigator (LSI) applications are completed for all potential participating sites and submitted to the VA CIRB through the overall PI. Once all applications receive final approval from the VA CIRB, the approved packages are sent to each specific site. Sites then make a final determination as to whether they will or will not participate. If they decide to participate, a copy of the VA CIRB minutes is forwarded to the site. The project is then reviewed in accordance with local R&D Committee policies and the VA CIRB is provided a copy of the site approval document prior to site initiation.

b. DoD Research Oversight

Human subjects research protection in the DoD is under the auspices of the Secretary of Defense and Director of Defense Research and Engineering. These offices oversee multiple components for the Army, Navy, Air Force, and others, each with their own mechanisms in place to ensure implementation of provisions of DoDD 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research).

Note: *The DoD is currently migrating their IRB review process for those with access to DoD computer networks to the online IRB submission and management program IRBNet®. This transition is expected to be complete by the end of FY 2011; however, some MTFs have already started using this system.*

Army Research Oversight

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

The Office of Research Protections (ORP) is located at the Medical Research and Materiel Command (MRMC) at Fort Detrick, Maryland, and ensures that MRMC-conducted, -contracted, -sponsored, -supported, or -managed research and U.S. Army Medical Command 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 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 compliance oversight program.

The ORP has four major subordinate offices: the Human Research Protection Office (HRPO), 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

All levels of research review and determinations are made by the Army Departments of Clinical Investigation (DCI), located at the major MTFs across the world. See Section III.3 of this Guidebook for a breakdown of DCI programs by region. The DCIs in the Army are designed and staffed to support the research efforts of the graduate medical education (GME) programs. They are also the administrative support for the MTF IRBs. Over the past number of years, this role has expanded to support all research efforts within each MTF where a DCI is located.

Headquarters-level review is required by the ORP for all studies being conducted at the MTFs. Certain MTF categories of protocols require preapproval by the headquarters office before they can receive an implementation letter. Those categories are investigational drug studies, investigational device studies, studies involving vulnerable populations as defined by 45 CFR 46, and studies that require third-party consent.

Studies that are funded by the MRMC must receive approval from the ORP office before funds for the project are released.

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 Section III.5) is the first action necessary to identify all institutions involved that meet the definition of engagement in research involving human subjects, thus requiring a Federal Assurance of Compliance and an IRB review.

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 Approval Timelines

Each MTF has a unique environment comprised of varying residency and fellowship training programs. 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 greater than six months for a greater than minimal risk (GTMR) study that requires full board review. Scientific review is required in advance of IRB review by the majority of MTFs. All protocols undergo an administrative review prior to IRB review. CRADAs /Material Transfer Agreements are also required for extramurally funded studies (monies arising outside the MTF). Please note that for multisite research involving more than one Army Medical Center, it is expected that the Headquarters MRMC IRB will serve as the central IRB for those protocols.

Navy Research Oversight

Navy research is conducted under the authority of the Navy Surgeon General through the Bureau of Medicine and Surgery (BuMed) and 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 and falls under the direction of the Navy Medical Research and Development Center (NMRDC). 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/facilities, or
- sponsored funding, regardless of source (intramural or extramural).

The DoN HRPP also supports the issuance of Navy Research Assurances. DoN HRPP guidance on Navy-sponsored research, for Navy Commands and extramural performers can be found at: http://www.med.navy.mil/BuMed/humanresearch/resource/Pages/DONHRPPGuidance.aspx#guidance_gen.

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. It is significant to note that 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 may be found at: http://www.med.navy.mil/BuMed/humanresearch/resource/AssuranceInformation/Pages/NavyAssurances.aspx. 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 three Navy Medical Centers: Naval Medical Center Portsmouth, National Naval Medical Center, and Naval Medical Center San Diego. These MCs 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 sites. This exists to expedite the approval of multi-center 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. Navy National Capitol Region typically takes 6 to 12 months from submission to approval. 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.

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 may 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 their 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 multi-site project is serial and can take between 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 Principal 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 between Departments. Along with ensuring that all the human subjects protections requirements are met, details about what and how data are shared need to be discussed and written into the protocol. 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.

Experienced research collaborators say the simplest way to share data across agencies is to keep all data to be shared in a coded, de-identified format. Data should also be kept in a separate, secure location (either virtual 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 treat identifiable data like patient data or Protected Health Information (PHI), so sharing identifiable data is particularly challenging. It is up to the PI (in consultation with their department's data/privacy officers) to determine which data are necessary and able to be shared in a coded, de-identified format. Data should also be kept in a separate, secure location (either virtual 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 treat identifiable data like patient data or Protected Health Information (PHI), so sharing identifiable data is particularly challenging. It is up to the PI (in consultation with their department's data/privacy officers) to determine which data is necessary and able to be shared.

Some clinicians, staff, or collaborators may need to be credentialed and privileged or given a special appointment, (e.g., without compensation [WOC] employees), depending on the type of data that 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 that they need.

a. Data Security Concerns

VA Data

In most cases, research data generated by VA investigators during the conduct of VA-approved research are owned by the VA, and their use and storage must meet all federal standards, including, (but not limited to): 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, and the Health Insurance Portability and Accountability Act (HIPAA).

In addition, there are a number of VA and VHA policies with which investigators and research staff must comply. More information on these policies is available online at: www.research.va.gov/resources/policies/docs/PI-Certification.pdf.

Clearly, there are many aspects of data and information security that need to be taken into consideration before embarking on a new VA research project. Most of these requirements need to be addressed in a research application and must be met before a protocol receives approval. Each VAMC has at least one Information Security Officer (ISO) and Privacy Officer who will review the IRB application for data security and privacy concerns. Additional information/data security considerations include the following:

- Access to VA computer systems is restricted (through virtual private network or VA network ID).
- To access VA computer systems, you must be a VA employee or have a WOC status appointment.
- 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.
- Encryption and password protection of all confidential data are required.

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 the VA data security concerns.

When national-level VA data with PHI are requested by a VA investigator, VA's Health Information Access program (HIA) will conduct a privacy compliance review based on a submission package from the researcher. Once legal requirements (i.e., 38USC7332, Privacy Act of 1974, and the HIPAA Privacy Rule) have been satisfied through the privacy compliance review, the VA researcher may be provided with access to the information requested, as described in the IRB-approved research protocol on the VA Intranet (http://vaww4.va.gov/hia/ResearchUsers.htm). 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) *Data Research Guide* is currently in production. Check with the Assistant Secretary of Defense for Health Affairs (ASDHA) office for updated status.

b. VA Data Agreements

There are a few data agreement options available to VA investigators whose projects require sharing data outside of the VA. In order to determine which agreement is best for you, speak with your local IRB Coordinator, ISO, or someone from the VA Technology Transfer Program (TTP). The following are some examples:

CRADA:

If there is a CRADA executed for the project (see Section II.4 of this Guidebook), there may be language included in it that details the use and sharing of the research data, including a timeline of expected deliverables. "CRADA data" means recorded information first produced by the parties, as required in the performance of the protocol. CRADA data do not include patient medical records or individually identifiable information, except for any that may be contained in the completed Case Report Form.

Data Collection Agreements

These are a type of CRADA used when projects meet all of the following criteria:

- The SOW calls for the retrospective or prospective collection of data from patient medical records, such as registries, 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.

Data Use Agreements (DUA)

These should be used to establish criteria for how data will be used, disclosed, stored, processed, and disposed of properly. These will also identify who will have access to and control of the information. 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;
- protects the confidentiality, integrity, and availability of the data;
- ensures data are destroyed once the approved use is completed; and
- must 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.
- Additional information and DUA templates are available within the VA at: http://vaww4.va.gov/hia/DUA.html.

Business Associate Agreement (BAA)

If a person or entity hired via contract must have access to PHI to perform the functions or services required by an agreement, in most cases, a BAA is required. Additional information on BAAs is available within the VA at: http://vaww.vhaco.va.gov/privacy/baa/vhabaawebtemplate.doc.

c. DoD Data Agreements

TRICARE Management Activity (TMA) DUA

TMA DUAs are used to request and control the disclosure and/or use of MHS data that are owned and/or managed by TMA. These DUAs are needed to ensure compliance with applicable Privacy Act and HIPAA privacy and security requirements. The approval of any DUA follows a comprehensive review and evaluation of the DUA request to ensure compliance with applicable DoD safeguards and requirements (see DoD 6025.18-R "Department of Defense Health Information Privacy Regulation," January 24, 2003, and DoD 8580.02-R, "Department of Defense Health Information Security Regulation," July 12, 2007), including requirements for storage and destruction. The TMA Privacy Office DUA team facilitates this process by confirming the following:

- DUA requests received are complete.
- 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, "DoD Health Information Privacy Regulation," January 24, 2003.
- Data file access methods ensure all PII and PHI are appropriately obtained.
- Any system(s) used to process and/or store MHS data owned and/or managed by TMA have appropriate physical, administrative, and technical safeguards in place; all authorized system users have proper privacy and security training; role-based access controls are in place; and reasonable measures are taken to avoid security risks and threats.
- 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, "Department of Defense Privacy Program," May 14, 2007.
- Action has been taken to incorporate a BAA into the primary contract, in accordance with DoD 6025.18-R, where appropriate.
- Timely receipt of a Certification of Data Destruction (CDD) is confirmed no later than 30 days after completion of a project or DUA expiration.
- Government personnel seeking to obtain MHS data to perform a sponsored project or study must send a completed DUA request to the TMA Privacy Office at duamail@tma.osd.mil or TMA Privacy Office, 5111 Leesburg Pike, Suite 810, Skyline 5, Falls Church, VA 22041. Each request must include the following: (a) a completed and signed current "DUA request template"; (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") and, in particular, requests for "all" data, PHI data, and social security numbers (SSNs) must be adequately justified; (c) TMA Human Subjects and Research Protection confirmation of a DoD IRB-approved protocol and/or a DoD survey requiring MHS-owned and/or managed data, if the DUA request is for research purposes (see the Common Rule); (d) TMA Privacy Board approval if the DUA request is for PHI and is for research purposes, where appropriate; and (e) approval and licensing report control symbol (RCS) from Washington Headquarter Services (WHS) and/or the Office of Management and Budget (OMB), if the project requires a survey.
- After receiving DUA approval, anyone needing access to information system applications or data sources must contact the responsible system program office. DUAs are active for one year, after which the Government

Representative responsible for the DUA must submit a renewal request or provide a CDD to the TMA Privacy Office.

Business Associate Agreement (BAA)

Contractors who provide services to the DoD and receive and/or create PHI in performance of the service must have a BAA incorporated into their contract, as required by DoD 6025.18-R, where appropriate.

Computer Matching Agreement (CMA)

A CMA defines the computerized comparison of two or more automated systems of records or a system of records with non-federal 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 non-federal agency for use in a computer matching program, except pursuant to a written agreement between the source agency and the recipient agency.

7. Media Relations/Public Affairs

You may want to share some 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 explains the procedures, responsibilities, and authority needed to ensure that VA research contributions are appropriately acknowledged and publicly disclosed. The VA Facility Director or their designee, the R&D Committee, the R&D Coordinator, ORD Communications Staff, and the Project 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 the VA.

Prior to any public submission of accumulated information, investigators must submit all publications or presentations to the locally designated review groups or individuals. This applies to all investigators, regardless of whether or not research support comes directly or indirectly from the VA, either in the form of funding or resources, or as a result of full-time, part-time, or WOC employment status. Inform the research office at the local VA facility at least eight weeks (or as early as possible) in advance of the expected publication, presentation, media interview, or professional activity where research results are being publicized, presented, recognized, or discussed. The acknowledgement of VA support and/or employment is essential and may be achieved following different procedures depending on the type of presentation:

- 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 as applicable specific research department).
- 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: Secure a written or, when not possible, a verbal agreement, that VA will be cited in news reports before participating in a media interview. Provide news media, prior to interviews, a

document on VA letterhead containing: the investigator's name, VA title, VA medical center, explanation of importance of VA, and preference that investigator's VA title be used when time limitations permit the use of only one professional title.

- VA acknowledgement during other professional activities: This may be verbal in some cases, such as receiving an award, or in writing in other cases, such as when accepting an appointment to a board.
- 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 release of information. There are Public Affairs Offices (PAOs) within each facility, and policies depend on the funding agency. Researchers must check with their relevant IRB and PAO before publication or 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 and may need to be reviewed by the PAOs at higher levels (such as BuMed).

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: (a) Research Director, (b) Service Chief, (c) Department Chief, (d) Department of Clinical Investigations/Human Subjects Protection Office, and (e) 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 is covered by BuMed INSTRUCTION 5721.3C and other related local command instructions.
- 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 U.S.C. 105 provides 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.

8. 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.

HEROES Project:
Dr. Karen Quigley, WRIISC, East Orange, NJ

Dr. Karen Quigley, a VA researcher in East Orange, NJ, began the HEROES (Healthy Resilience After Operational and Environmental Stressors) study in 2005 to measure and track the psychosocial health of National Guard and Army Reserve troops, looking for factors that predict vulnerability to medically unexplained symptoms and poor functional status. Dr. Quigley partnered with an experienced and knowledgeable DoD collaborator, Col. Charles Engel, MD, MPH of the Uniformed Services University and Walter Reed Army Medical Center (WRAMC) at the recommendation of trusted mutual colleagues.

Dr. Engel's active problem solving was essential in overcoming challenges due to limited space and other resources at one of the project sites. Dr. Engel helped Dr. Quigley identify and brief leaders who could offer access to soldiers for study, develop briefing content that anticipated and addressed military leader concerns, petition command for precious space to perform essential research assessments, and validate that the Army was a committed study partner when VA R&D leaders reviewed study viability in the face of unforeseeable sources of delay.

Dr. Quigley reported that the project start-up took much longer than typical studies and longer than she had anticipated. During this time as a VA research scientist and Associate Director for Research at the New Jersey War Related Illness and Injury Study Center (WRIISC), a national VA center, she was supported by VAMC infrastructure.

This support provided additional personnel to support the study. When the study encountered difficulties in recruitment efforts at Fort Dix, a Health Services Research and Development (HSR&D) project modification grant allowed Dr. Quigley to change the project scope and provided her with additional funding. This additional support included a travel budget which she said was absolutely essential in providing funds for travel related to study recruitment and briefings to key DoD leaders at the Army 3-Star level as well as initial and new command staff at military deployment platforms. Dr. Quigley's success in implementing project modifications involved the cooperation and financial support of the local Research Enhancement Award Program (REAP) Center Director, the NJ WRIISC Center Director, and upper-level administration at HSR&D.

Dr. Quigley reported that the single most important ingredient for the success of this VA/DoD study was working with a collaborator who had strong networks within the DoD and was highly engaged in insuring the project's success.

Severe Traumatic Brain Injury (TBI) Studies:
Dr. Theresa Pape

Investigator Dr. Theresa Pape, a VA researcher with a Rehabilitation Research and Development (RR&D) funded study (*Can neural adaptation after severe brain injury be facilitated?*) hoped to include research subjects referred from MTF to a VA medical facility for rehabilitation and/or to include a DoD site. However, she ran into a series of challenges as she tried to get the project underway. Despite many attempts by the VA site PI, patients were not referred from the

MTF to the VA for acute rehabilitation. Dr. Pape had also, during grant conceptualization, engaged a colleague who had agreed to serve as PI at WRAMC, but due to the pending transition of patients from WRAMC to Bethesda Naval Hospital, which subsequently limited the number of appropriate subjects there, the plan to include WRAMC as a site was abandoned. Despite many attempts at networking, Dr. Pape was unable to identify a willing site PI at Bethesda Naval Hospital. Thus, she was unable to initiate a VA/DoD research collaboration.

The lack of referrals to the VA for rehabilitation and the loss of the proposed DoD site created a setback for recruitment and delayed the project's start-up and progress. As DoD clinicians do not have protected time for research, this type of challenge is not uncommon. Because Dr. Pape was not able to engage a prospective PI, she did not have the opportunity to explore options that may have made this collaboration more feasible and attractive for a DoD PI at Bethesda Naval Hospital. Dr. Pape eventually overcame recruitment challenges by expanding recruitment efforts at one of her community-based study sites.

Dr. Pape encountered another difficulty related to IRB approval of a protocol, "Measurement and Outcomes Post Severe Brain Injury," at both the VA and DoD. She discovered that the VA and DoD had differing interpretations of ethical research. The military sites asked that the investigator explain and even promise potential direct subject benefit, while at the VA sites the investigator need not promise direct subject benefit or potential benefit if the results of the research had the intent to benefit society or others in the future. The latter interpretation placed Dr. Pape in a position of conflict, and the PI was not able to conceive of a reasonable solution that did not violate basic ethical principles. The project was not conducted at the military site in large part because of this impasse. Dr. Pape and colleagues wrote about these unresolved legal and ethical issues in a manuscript for the *Journal of Rehabilitation Research and Development (JRRD).*

<u>Community Reintegration Project:</u>
<u>Dr. Linda Resnik, PVAMC, Providence, RI</u>

In 2007, members of the Center for the Intrepid (CFI) Occupational Therapy (OT) Department were searching for an outcome measure to assess the results of their community reintegration program. Captain Melissa Gray reached out to Dr. Linda Resnik, a VA Research Health Scientist at the Providence VA Medical Center (PVAMC), to learn more about her work to develop the CRIS, a measure of community reintegration for service members. At that time, Dr. Resnik's tool was still under development, and the CFI clinical staff expressed interest in collaborating on a study to validate the measure in their population. Dr. Resnik applied for and received a VA HSR&D service directed grant that provided money for her team to visit San Antonio to plan the research collaboration, and later funded a study based at the CFI.

Although Dr. Resnik had not previously collaborated with a DoD site, and the CFI site PI was a clinician with no prior research experience, both were guided through the process of setting up the study by the CFI's Research Director, COL Rachel Evans. At the initial planning meeting, COL Evans arranged for Dr. Resnik to meet with key stakeholders from the CFI and Brooke Army Medical Center, including leadership from the clinical departments, the IRB, and CFI administrators. This face-to-face meeting provided an opportunity for all interested parties to meet with Dr. Resnik; learn about her research; exchange ideas and provide input on recruitment strategies, human subjects concerns, and other logistical considerations. Following the meeting, Dr. Resnik worked with the CFI staff to submit the research proposal to both the DoD and PVAMC IRBs and identify and hire a Research Assistant (RA) who was contracted through the PVAMC. This planning process took many months.

Despite a series of challenges related predominantly to personnel turnover, the study

was completed successfully, although with some delay. The initial site PI was transferred to Hawaii and the new site PI was also transferred. Thus, there were three site PIs over the course of the study. The RA who began the study took another job, and there were delays as a new RA was identified, contracted and trained. Throughout this process, Dr Resnik communicated regularly with the CFI's Research Director to identify solutions.

Successful experience with this project and the mutual trust and respect developed through working together paved the way for Dr. Resnik's second, larger research collaboration with the CFI, which is currently underway.

Mentored Research Training Initiative:
Dr. Rory Cooper, HERL, Pittsburgh, PA

The Human Engineering Research Lab (HERL) at the VA Pittsburgh Healthcare System has been a presence at the VA-sponsored National Veterans Wheelchair Games (NVWG) since 2000, the National Disabled Veterans Winter Sports Clinic (NDVWSC) since 2006, and starting in September 2010 at the National Veterans Summer Sports Clinic (NVSSC). These events have provided the lab and Dr. Rory Cooper, Founding Director and VA Senior Research Career Scientist from the VA RR&D Center of Excellence in Pittsburgh, with an opportunity to disseminate research results, educate wheelchair users on their work, and recruit wheelchair users to participate in studies.

Dr. Cooper collaborates with Dr. Paul Pasquina of WRAMC on medical staff training and on studies conducted annually during these events. Their collaborative project provides "hands-on" mentored research training experience in the field of rehabilitation for military clinical personnel providing direct care to service members and Veterans and improves knowledge regarding the conduct of clinical research and its impact. Trainees are involved in project development, subject recruitment, data collection, data analysis/interpretation, and dissemination of results. Over the years, more than 25 studies, including some multiple year studies, have been conducted involving 19 medical residents and 3 physicians from WRAMC working with the Human Engineering Research Lab's multidisciplinary team.

A critical factor in this project's success and growth is the ongoing collaboration between Dr. Cooper and Dr. Pasquina. The residency directors and program directors at WRAMC are very supportive of this program. The DoD provides the time and travel funding for their staff attending the events. Dr. Cooper schedules in-person meetings with WRAMC personnel who participate in this research program to provide mentorship and facilitate the process of preparing a scientific abstract and journal article.

The State of the Science Symposia Series, developed in 2005, has been a mechanism for WRAMC PM&R residents and attending physicians to get to know Dr. Cooper and the research conducted by HERL. The Symposia Series increases interest in this program.

Dr. Cooper reported that developing rapport with collaborating sites is of utmost importance to the initial and ongoing development of this program. Demonstrating dedication to the research trainees by providing ongoing training and guidance also improves the overall process.

Empirically Based Cognitive Rehabilitation:
The SCORE! Study Collaboration

When Michael Jaffe, MD, National Director of the Defense and Veteran's Brain Injury Center (DVBIC), was approached about developing a study to assess the efficacy of cognitive rehabilitation for Operation Iraqi Freedom/Operation Enduring Freedom (OEF/OIF) service members with mild traumatic brain injury, he turned to Rodney Vanderploeg, PhD. Dr. Vanderploeg had successfully completed a multicenter, randomized clinical trial of rehabilitation interventions for traumatic brain injury in collaboration with DVBIC and his colleagues at the VA Polytrauma Rehabilitation Centers. As Clinical Director of the Brain Injury Rehabilitation program at the James A. Haley Veterans Hospital and a DVBIC investigator, he believed that a similar collaboration would be

required to successfully design and carry out the study. DVBIC has played a critical role in military TBI research as a funding source for research projects, hiring researchers and support staff to carry out these projects, and has served as a mediating agency to bridge the gap between DoD and VA systems.

To implement the cognitive rehabilitation project, Dr. Vanderploeg turned to Douglas Cooper, PhD, and Amy Bowles, MD, in the Traumatic Brain Injury Service at Brooke Army Medical Center (BAMC) for potential collaboration. The three had worked together on the joint VA/DoD Clinical Practice Guidelines for Management of Concussion/Mild Traumatic Brain Injury. Through their collaboration on those guidelines, they developed a strong working alliance and a greater appreciation of the similarities and differences in working with mTBI patients in the DoD and VA healthcare systems. The TBI service at BAMC offered an experienced, multidisciplinary rehabilitation team, the research infrastructure necessary to support the study, and a history of successful research collaboration with DVBIC. They decided to focus on individuals with more chronic symptomatology so that it would have greater application in both the VA and DoD populations.

An executive committee made up of subject-matter experts from DVBIC (Drs. Kennedy, French, and Manion), the VA (Drs. Vanderploeg and Cornis-Pop), and the DoD (Drs. Cooper and Bowles) convened to develop an executive summary and outline of the project, named the Study of Cognitive Rehabilitation Effectiveness (SCORE). Deciding upon research aims, hypotheses, and a research plan posed no difficulty for the group. Delineating responsibilities between the various collaborating partners in the project proved more challenging. Unlike traditional clinical or research projects where budget, manpower, and oversight are internally controlled, the responsibilities for carrying out the SCORE study needed to be divided among the groups. Procurement of supplies, hiring actions, and database development fell under the control of DVBIC. Implementing the study became the responsibility of the team from BAMC. To develop the treatment manual, VA researchers Drs. Vanderploeg and Cornis-Pop contacted their team of collaborators from the original DVBIC/VA multi-site, randomized treatment trial. The expertise and experience of the VA therapists proved immeasurable in drafting the treatment manual and fostering the professional development of the team of BAMC therapists.

When the final product was submitted to the IRB at BAMC, the investigators included team members from DoD, DVBIC, and VA healthcare systems. Despite this somewhat atypical arrangement, leveraging the strengths of these three institutions allowed for the creation of a research product that was greater than the sum of the parts. The SCORE study became a true collaborative project.

<u>National Survey of Service Members and Veterans from Vietnam and OIF/OEF with Major Traumatic Limb Loss:</u>

<u>Dr. Gayle Reiber, VA Puget Sound, Seattle, WA</u>

PIs Gayle Reiber, a VA Senior Scientist from VA Puget Sound, and Douglas G. Smith, an orthopedic surgeon from Harborview Hospital and Injury Center and the University of Washington, submitted a proposal to the VA HSR&D to conduct a national survey of prosthetic use in service members and Veterans from Vietnam and OIF/OEF with major traumatic limb loss. This survey was to include all eligible OIF/OEF service members and an equivalent number of Vietnam Veterans with major traumatic limb loss. Dr. Smith, an expert in surgical and rehabilitation aspects of amputation, served as a surgical consultant to WRAMC and BAMC after the onset of the OEF/OIF conflicts and shared his expertise and new techniques with surgeons who had little recent amputation experience. The study included an expert panel, a group of experts in limb loss and prosthetic care from VA, DoD, academic, and private-practice settings. All members of the

expert panel submitted letters of support indicating willingness to work with the PIs.

The investigators used the conventional approach to survey research in the United States and received a waiver of consent and authorization in accordance with HIPAA Common Rule 45 CFR 46 from VA Puget Sound and the University of Washington. Eligible Veterans were mailed an information statement and survey and could then participate by completing and returning the survey or not returning a survey. An extra step, required by the Walter Reed Human Research Protection, involved Walter Reed staff contacting each individual by mail and asking for consent to send the information statement and survey. This step had the potential to markedly reduce survey participation. In view of the differing approaches proposed, the matter was referred to JAG, who indicated there was "no appropriate mechanism to share contact information for subjects eligible for the study."

PIs working with a DoD investigator at the Madigan Army Medical Center submitted the study and received approval. Then a Madigan employee, using the M-2 database, identified eligible individuals and contacted them with the study information statement and survey. Since only active military are included in the M-2 database, only 25% of eligible OEF/OIF participants were identified. A two-year effort to obtain the full roster of potential participants with major traumatic limb loss from OEF/OIF was resolved when senior healthcare leaders in both agencies agreed upon an acceptable strategy to transfer the limited contact information from Walter Reed to the VA.

Once identifying information for eligible OEF/OIF service members was received at the VA, the survey was completed with a response rate of 62%, and the results are reported in a single-topic issue of *JRRD* on traumatic limb loss (Vol 47, Issue 4, 2010).

9. Recommendations

VA and DoD investigators stand ready and willing to collaborate. Despite the challenges and complexities, research teams have met with many successes. Yet there are many collaborative projects that were never able 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 the VA and DoD could work together to remove some of the barriers and facilitate greater research collaboration efforts. 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. Finally, there are several recommendations that must be addressed at the Congressional level:

- 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 with legislative members to appropriate more funding of joint VA/DoD research centers and collaborations.
- Work within Departments to enable the VA and DoD to recognize the authority of each other's IRB as the IRB of record.
- Develop overarching MOUs to facilitate potential research collaborations, insuring that these are broadly written to facilitate collaboration rather than limit it.
- Develop mechanisms to facilitate exchange of VA and DoD research data through umbrella agreements, new policies, and innovative mechanisms.
- Develop model agreements for VA/DoD CRADAs, IAAs, and MOAs for interagency studies.

- Provide opportunities for preproposal scientific review prior to research proposal submission and IRB protocol submission to assist new investigators in navigating scientific and human subjects issues.
- Work with Congressional leadership to provide new funding opportunities through the VA to create a clinical and research mission jointly supported by the VA and DoD.
- Work with government leaders to recognize the unique role of the VA in following service members from separation from active duty throughout 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 in order to improve understanding of and participation in bi-agency research.

Section III. Appendix: Helpful Resources

1. VA/DoD Research Collaboration Acronyms

(VA in *italics,* DoD in **bold,** both in plain font)

AAHRPP	Association for the Accreditation of Human Research Protection
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 Modernization**
AFB	**Air Force Base**
AFMSA	**Air Force Medical Support Agency**
AFOSR	**Air Force Office of Scientific Research**
AHLTA	**Armed Forces Health Longitudinal Technology Application**
AHRPO	**Army Human Research Protection Office**
AFRL	**Air Force Research Lab**
AKO	**Army Knowledge Online**
AMC	**Army Medical Center**
AMEDD	**Army Medical Department**
ANG	**Air National Guard**
AO	Administrative 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**
BAA	Business Associate Agreement, also
BAA	**Broad Agency Announcement**
BAG	**Budget Activity Group**
BLR&D	*Biomedical Laboratory Research & Development Service*
BuMed	**Bureau of Medicine and Surgery**
CAGE	Commercial and Government Entity
CAREN	**Computer Assisted Rehabilitation Environment**
CBOC	*Community-Based Outpatient Clinic*
CCR	Central Contractor Registry
CDD	**Certificate of Data Destruction**
CDMRP	**Congressionally Directed Medical Research Programs**
CFI	**Center for the Intrepid**

CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practices
CHAMPUS	**Civilian Health and Medical Program of the Uniformed Services**
CHAMPVA	**Civilian Health and Medical Program of Veterans Affairs**
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
CO	*Central Office*
COACH	**Center on Advice and Compliance Help**
COE	Centers of Excellence
COI	Conflict of Interest
COS	Chief of Staff
CPRS	Computerized Patient Record System
CR	Contract Representative
CRADA	Cooperative Research and Development Agreement
CRADO	*Chief Research and Development Officer*
CSI	**Congressional Special Interest**
CSP	Cooperative Studies Program
CSR&D	*Clinical Science Research & Development Service*
DARPA	**Defense Advanced Research Project Agency**
DCI	**Department of Clinical Investigation**
DCC	Data Consent Committee (HIPAA abbreviation)
DCO	**Defense Connect Online**
DDR&E	**Director of Defense Research & Engineering**
DFARS	**Department of Defense Federal Acquisition Regulation Supplement**
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**
DKO	**Defense Knowledge Online**
DMC	*Data Monitoring Committee*
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
DSMB	*Data Safety and Monitoring Board*
DSMO	Designated Standard Maintenance Organization (HIPAA abbreviation)
DTIC	**Defense Technical Information Center**

DTRA	**Defense Threat Reduction Agency**
DUA	Data Use Agreement
DUNS	Data Universal Number System
DVA	Department of Veterans Affairs
DVBIC	**Defense and Veterans Brain Injury Center**
EHR	**Electronic Health Record**
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ePROMISE	*Electronic Project Management and Information System*
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
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 Equivalent (FTE)
FY	Fiscal Year
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*
HCP	Healthcare Provider
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 Protection Office**
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*
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
IATO	**Interim Authorization to Operate**
IDE	Investigational Device Exemption
IIR	*Investigator Initiated Research*
IND	Investigational New Drug
IO	Institutional Officer
IP	Integration Panel
IPA	Intergovernmental Personnel Act
IRB	Institutional Review Board
IRBO	Institutional Review Board Office
IRM	Information Resources Management
ISO	Information Security Office
ISR	**Institute of Surgical Research**
IT	Information Technology
J&A	Justification and Approval
JRRD	Journal of Rehabilitation Research and Development
JFCOM	**Joint Forces Command**
JPRP	Joint Programmatic Review Panel
JSLIP	Joint Senior Leadership Integration Panel
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
MOU	Memorandum of Understanding
MRMC	**(see USAMRMC)**
MTF	**Military Treatment Facility**
NAMRL	**Naval Aerospace Medical Research Lab**
NCCOSC	**Navy Center for Combat and Operational Stress Control**
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**
NICoE	**National Intrepid Center of Excellence**
NIH	National Institute 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 Center**
NMRU	**Naval Medical Research Unit**
NNMC	**National Naval Medical Center**
NPC	Nonprofit Corporation
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**
OEF	**Operation Enduring Freedom**
OER	Office of Extramural Research
OGC	Office of General Council
OGE	Office of Governmental Ethics
OHRP	Office of Human Research Protections (HHS)
OIF	**Operation Iraqi Freedom**
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**
ORD	*Office of Research Management*
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)**
PAO	Public Affairs Office
PD	Project Director
PHI	Protected Health Information

PHRP	Partnership for Human Research Protection
PI	Principal Investigator
PII	Personally Identifiable Information
P.L.	Public Law
POC	Point of Contact
PRC	*Polytrauma Rehabilitation Center*
PRIDE	*Program for Research Integrity, Development and Education*
PT/BRI	Polytrauma and Blast-Related Injury
PTSD	Post Traumatic Stress Disorder
QA	Quality Assurance
QUER	*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*
RFP	Requests for Proposals
RIO	Research Integrity Officer
RMC	**Regional Medical Center**
RNIHS	Research Not Involving Human Subjects
RR&D	*Rehabilitation Research & Development*
RRP	*Rapid Response Projects*
SAQ	System Assurance Questionnaire
SCI	Spinal Cord Injury
SDR	*Service Directed Research*
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**
ST	**Science/Technology**

T2	**Technology Transfer**
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**
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**
USAF	**United States Air Force**
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 for Chemical Defense**
USAMRIID	**US Army Research Institute of Infectious Diseases**
USAMRMC	**US Army Medical Research and Materiel Command**
USARIEM	**United States Army Research Institute of Environmental Medicine**
USC	**United States Code**
USN	**United States 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*
VHA	*Veterans Health Administration*
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
WOC	*Without Compensation*
WHS	**Washington Headquarter Services**
WII	**Wounded, Ill, and Injured program**
WRAIR	**Walter Reed Army Institute of Research**
WRAMC	**Walter Reed Army Medical Center**
WRIISC	**War Related Illness and Injury Study Center**

2. VA/DoD Collaboration Checklist for Investigators

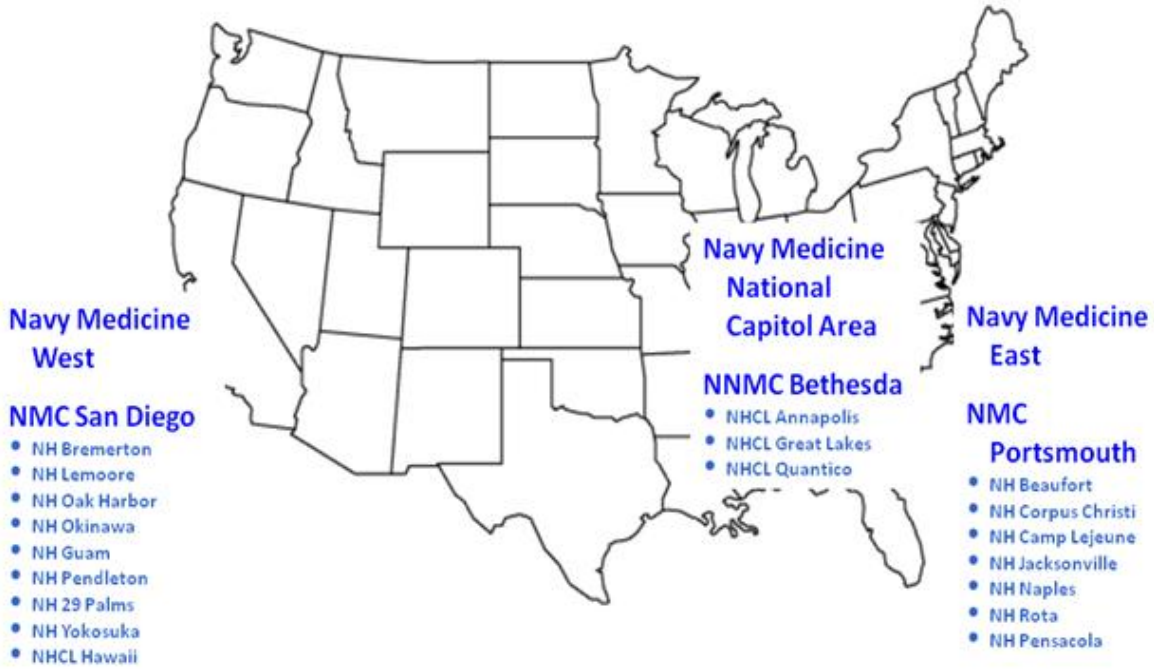
Proposal Preparation/Project Planning Phase	
	1. Identify collaborator(s) at participating institutions
	2. Develop proposal idea (with specific aims that identify a significant problem of importance to the VA/DoD)
	3. Meet with potential collaborators (in-person, if possible) to discuss project details
	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 co- investigators and collaborators
	7. Develop budget
	8. Meet with administrative personnel at both agencies to confirm plans for research administration (space, hiring plans, equipment/supplies and other budget needs etc.)
	9. 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 to initiate the study at involved sites.
	2. Submit the protocol to all applicable committees (i.e. IRB, safety) at each participating site
	3. Finalize and sign all agreements (i.e., CRADA, MOU, contract, IPA, data use)
	4. Begin contracting and hiring procedures
	5. Train project staff and develop project standard operating procedures for research integrity, data sharing, media and public relations.
	6. Conduct research project

3. 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 Army Medical Center, Washington, DC	• WRAMC, WAMC & KACH have IRBs • MRMC is not part of the CIP
DeWitt Army Community Hospital, Fort Belvoir, VA	
Kimbrough Ambulatory Care Center, Fort Meade, MD	
(IRB) Womack Army Medical Center, Fort Bragg, NC	
(IRB) Keller Army Community Hospital, West Point, NY	
Northern RMC (P), Fort Belvoir, VA	
Ireland Army Community Hospital, Fort Knox, KY	
Guthrie Medical Department Activity, Fort Drum, NY	
Kenner Army Health Clinic, Fort Lee, VA	
McDonald Army Community Hospital, Fort Eustis, VA	
Southern Region (SRMC)	
(IRB) Brooke	• BAMC and DDEAMC have IRBs
Carl R. Darnall Army Medical Center, Fort Hood, TX	
Reynolds Army Community Hospital, Fort Sill, OK	
Bayne Jones Army Community Hospital, Fort Polk, LA	

(IRB) Dwight D. Eisenhower AMC, Fort Gordon, GA	
Blanchfield Army Community Hospital, Fort Campbell, KY	
Fox Army Health Center, Redstone Arsenal, AL	
Lyster Army Health Clinic, Fort Rucker, AL	
Martin Army Community Hospital, Fort Benning, GA	
Moncrief Army Community Hospital, Fort Jackson, SC	
Winn Army Community Hospital, Fort Stewart, GA	
Western Region (WRMC)	
(RMC) (IRB) Madigan Army Medical Center, Fort Lewis, WA	• MAMC and WBAMC have IRBs
Evans Army Community Hospital, Fort Carson, CO	
Bassett Army Community Hospital, Fort Wainwright, AK	
Weed Army Community Hospital, Fort Irwin, CA	
(IRB) William Beaumont Army Medical Center, Fort Bliss, TX	
Bliss Army Health Center, Fort Huachuca, AZ	
General Leonard Wood Army Community Hospital, Fort Leonard Wood, MO	
Irwin Army Community Hospital, Fort Riley, KS	
Munson Army Health Center, Fort Leavenworth, KS	
Pacific Region (PRMC)	
Camp Zama, Japan	• TAMC is IRB for 18th MEDCOM
Tripler Army Medical Center (TAMC), Honolulu, HI	
Korea	

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



Navy Medicine East	
NMC Portsmouth	• IRB at NMC Portsmouth
NH Camp Lejeune	
NH Jacksonville	
NH Pensacola	
NH Corpus Christi	
NH Beaufort	
Naval Operational Medicine Institute	
NH Rota	
EMF Kuwait	
NH Naples	
Navy Medicine National Capitol Area	
NNMC Bethesda	• IRB at NNMC
NHCL Annapolis	
NHCL Quantico	
Pacific Region (PRMC)	
NMC San Diego	• IRB at NMC San Diego
NH Bremerton	
NH Pendleton	
NH Oak Harbor	
NH 29 Palms	
NH Lemoore	
NHCL Hawaii	
NH Okinawa	
NH Yokosuka	
NH Guam	

5. Templates/Sample Documents

VA Templates

- VA Research Funding editable forms are available at the VA Intranet R&D website: http://vaww.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 and/or extraction of PII and/or PHI data (encrypted or not) from systems that are owned and/or managed by TRICARE Management Activity (TMA).
- Instructions for Completing PII, PHI and/or LDS DUA
- De-Identified (DIF) DUA: Submit if your project requires access to and/or extraction of MHS data that have been de-identified in accordance with subparagraph C8.1.3 of DoD 6025.18-R.
- 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 DUA will be placed on a system that has not been granted a DoD Authorization to Operate (ATO) or an Interim Authorization to Operate (IATO).
- Change in DUA: Submit to change the Sponsor on an existing DUA.
- Change in DUA: Submit to change the Custodian on an existing DUA.
- DUA: Submit to modify an existing DUA.
- DUA: Submit to request a 30-day extension on an existing DUA.
- DUA: Submit to renew an existing DUA.
- 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 DUA.

6. 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

7. Hyperlinks used in the Guidebook and their websites (by page #)

1	Pub. L. 108–375 (National Defense Authorization Act for 2005) http://www.law.cornell.edu/usc-cgi/get_external.cgi?type=pubL&target=108-375
	118 Stat. 2128 (National Defense Authorization Act for 2006) http://www.law.cornell.edu/usc-cgi/get_external.cgi?type=statRef&target=date:Oct.%2028,%202004ch:nonestatnum:118_2128
3	Uniformed Services University of the Health Sciences http://www.usuhs.mil/
12	Telemedicine & Advanced Technology Research Center http://www.tatrc.org/
15	Introduction to the Responsible Conduct of Research http://ori.hhs.gov/education/products/RCRintro/
17	Code 34 (Navy Warfighter Performance Department) http://www.onr.navy.mil/Science-Technology/Departments/Code-34.aspx
19	Oak Ridge Institute for Science and Education (ORISE) fellowships http://see.orau.org/
21	FAR 52.217-8 (Solicitation Provisions and Contract Clauses) https://www.acquisition.gov/far/html/FARTOCP52.html
23	15 U.S.C. 3710a (CRADAs) http://uscode.house.gov/download/pls/15C63.txt
25	45 CFR 46 (HHS Protection of Human Subjects) http://ohsr.od.nih.gov/guidelines/45cfr46.html
	21 CFR 50 (FDA Protection of Human Subjects) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50
	38 CFR 16 (VA Protection of Human Subjects) http://www.access.gpo.gov/nara/cfr/waisidx_02/38cfr16_02.html
	10 USC 980 (DoD Limitation On Use Of Humans As Experimental Subjects) http://www.med.navy.mil/sites/nmrcd/rap/Documents/10_USC_980.pdf
	DoDD 3216.02 (DoD Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research) http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf
	32 CFR 219 (OSD Protection of Human Subjects) http://www.tricare.mil/hpae/_docs/32cfr219.pdf
	SECNAVINST 3900.39D (Navy Human Research Protection Program) http://www.fas.org/irp/doddir/navy/secnavinst/3900_39d.pdf
	Office of Research Oversight http://www1.va.gov/ORO/About_ORO.asp
26	Program for Research Integrity Development & Education http://www.research.va.gov/PRIDE/
	VA Handbook 1200.1 (VA Research & Development Committee) http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2038
	VA Central IRB http://www.research.va.gov/vacentralirb/default.cfm
31	38 USC 7332 (VA Confidentiality of certain medical records) http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+38USC7332
	Privacy Act of 1974 http://www.justice.gov/opcl/privstat.htm
	HIPAA Privacy Rule http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html

32	DoD 6025.18-R "Department of Defense Health Information Privacy Regulation," January 24, 2003 http://www.dtic.mil/whs/directives/corres/pdf/602518r.pdf
	DoD 8580.02-R, "Department of Defense Health Information Security Regulation," July 12, 2007 http://www.dtic.mil/whs/directives/corres/pdf/858002rp.pdf
33	DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007 http://www.dtic.mil/whs/directives/corres/pdf/540011r.pdf
	VHA Handbook (Presentation of Research Results Handbook) http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1766
34	BuMed INSTRUCTION 5721.3C (Navy Approval process for presentations and publication of professional manuscripts, authored works and articles) http://www.med.navy.mil/directives/ExternalDirectives/5721.3C.pdf
35	Title 17 U.S.C. 105 & 101 (Subject Matter and Scope of Copyright) http://www.copyright.gov/title17/92chap1.html
49	Walter Reed Army Medical Center, Washington, DC http://www.wramc.amedd.army.mil/Pages/default.aspx
	DeWitt Army Community Hospital, Fort Belvoir, VA http://www.dewitt.wramc.amedd.army.mil/default.aspx
	Kimbrough Ambulatory Care Center, Fort Meade, MD http://kacc.narmc.amedd.army.mil/default.aspx/
	(IRB) Womack Army Medical Center, Fort Bragg, NC http://www.wamc.amedd.army.mil/Pages/default.aspx
	(IRB) Keller Army Community Hospital, West Point, NY http://kach.amedd.army.mil/index/index.html
	Northern RMC (P), Fort Belvoir, VA http://www.narmc.amedd.army.mil/Pages/default.aspx
	Ireland Army Community Hospital, Fort Knox, KY http://www.iach.knox.amedd.army.mil/body.asp?M=3&PI=141&HS=False&HL=False
	Guthrie Medical Department Activity, Fort Drum, NY http://www.drum.amedd.army.mil/
	Kenner Army Health Clinic, Fort Lee, VA http://kenner.narmc.amedd.army.mil/default.aspx/
	McDonald Army Community Hospital, Fort Eustis, VA http://mcdonald.narmc.amedd.army.mil/default.aspx
	(IRB) Brooke http://www.sammc.amedd.army.mil/staff/research/dci/index.asp
	Carl R. Darnall Army Medical Center, Fort Hood, TX http://www.crdamc.amedd.army.mil/default.asp?page=index
	Reynolds Army Community Hospital, Fort Sill, OK http://www.rach.sill.amedd.army.mil/
	Bayne Jones Army Community Hospital, Fort Polk, LA http://www.polk.amedd.army.mil/
50	(IRB) Dwight D. Eisenhower AMC, Fort Gordon, GA http://www.med.navy.mil/sites/nhbeaufort/Pages/Welcome_Page.aspx
	Blanchfield Army Community Hospital, Fort Campbell, KY http://www.campbell.amedd.army.mil/
	Fox Army Health Center, Redstone Arsenal, AL http://www.redstone.amedd.army.mil/
	Lyster Army Health Clinic, Fort Rucker, AL http://www.rucker.amedd.army.mil/
	Martin Army Community Hospital, Fort Benning, GA http://www.martin.amedd.army.mil/

50	Moncrief Army Community Hospital, Fort Jackson, SC http://www.moncrief.amedd.army.mil/
	Winn Army Community Hospital, Fort Stewart, GA http://www.winn.amedd.army.mil/
	(RMC) (IRB) Madigan Army Medical Center, Fort Lewis, WA http://www.mamc.amedd.army.mil/
	Evans Army Community Hospital, Fort Carson, CO http://evans.amedd.army.mil/
	Bassett Army Community Hospital, Fort Wainwright, AK http://www.afhcp.org/bassett-army-community-hospital/
	Weed Army Community Hospital, Fort Irwin, CA http://www.irwin.amedd.army.mil/
	(IRB) William Beaumont Army Medical Center, Fort Bliss, TX http://www.wbamc.amedd.army.mil/
	Bliss Army Health Center, Fort Huachuca, AZ http://rwbach.huachuca.amedd.army.mil/
	General Leonard Wood Army Community Hospital, Fort Leonard Wood, MO http://glwach.amedd.army.mil/
	Irwin Army Community Hospital, Fort Riley, KS http://iach.amedd.army.mil/
	Munson Army Health Center, Fort Leavenworth, KS https://www.munson.amedd.army.mil/
	Tripler Army Medical Center (TAMC), Honolulu, HI http://www.tamc.amedd.army.mil/
51	NMC Portsmouth http://www.med.navy.mil/sites/nmcp/Pages/default.aspx
	NH Camp Lejeune http://www.med.navy.mil/sites/nhcl/Pages/default.aspx
	NH Jacksonville http://www.med.navy.mil/sites/nhjax/Pages/default.aspx
	NH Pensacola http://www.med.navy.mil/sites/pcola/Pages/default.aspx
	NH Corpus Christi http://www.med.navy.mil/sites/nhccc/Pages/default.aspx
	NH Beaufort http://www.med.navy.mil/sites/nhbeaufort/Pages/Welcome_Page.aspx
	Naval Operational Medicine Institute http://www.med.navy.mil/sites/navmedmpte/nomi/Pages/default.aspx
	NH Rota http://www.med.navy.mil/sites/nhrota/Pages/Home.aspx
	NH Naples http://www.med.navy.mil/sites/napoli/Pages/default.aspx
	NNMC Bethesda http://www.bethesda.med.navy.mil/
	NHCL Annapolis http://www.med.navy.mil/sites/annapolis/Pages/default.aspx
	NMC San Diego http://www.med.navy.mil/sites/nmcsd/Pages/default.aspx
	NH Bremerton http://www.med.navy.mil/sites/nhbrem/Pages/default.aspx
	NH Pendleton https://cpen.med.navy.mil/

51	NH Oak Harbor http://www.med.navy.mil/sites/nhoh/Pages/default.aspx
	NH 29 Palms http://www.med.navy.mil/sites/nhtp/Pages/default.aspx
	NH Lemoore http://www.med.navy.mil/sites/nhlem/Pages/default.aspx
	NHCL Hawaii http://www.med.navy.mil/sites/nhch/Pages/default.aspx
	NH Okinawa http://www.med.navy.mil/sites/nhoki/Pages/default.aspx
	NH Yokosuka http://www.med.navy.mil/sites/nhyoko/Pages/default.aspx
	NH Guam http://www.med.navy.mil/sites/usnhguam/Pages/default.aspx
52	Personally Identifiable Information (PII), Protected Health Information (PHI), and/or Limited Data Set (LDS) Data Use Agreement (DUA http://www.tricare.mil/tma/privacy/downloads/TMA%20Data%20Use%20Agreement%20Template%20for%20PII-PHI-LDS%20Data%20Rev%207-22-2010.doc.
	Instructions for Completing PII, PHI and/or LDS DUA http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Instructions Final rev 6-24-2010.doc
	De-Identified (DIF) DUA http://www.tricare.mil/tma/privacy/downloads/2010630/De-identified DUA template.doc
	DoD 6025.18-R. (Health Information Privacy Regulation) http://www.dtic.mil/whs/directives/corres/pdf/602518r.pdf
	DUA http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Subcontractor Letter.doc
	System Security Verification http://www.tricare.mil/tma/privacy/downloads/FINAL_APPROVED_SSV_Locked.doc
	Change in DUA http://www.tricare.mil/tma/privacy/downloads/2010630/Change in DUA Sponsor Template.doc
	Change in DUA Custodian http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Change in Custodian Template.doc
	DUA http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Modification Request Template.doc
	DUA http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Extension Request Letter.doc
	DUA http://www.tricare.mil/tma/privacy/downloads/2010630/DUA Renewal Request Letter.doc
	Certification of Data Destruction http://www.tricare.mil/tma/privacy/downloads/20100204/Certification of Data Destruction