VHA Office of Research and Development

Manual for Associate Chiefs of Staff and Administrative Officers for Research

Version 5.0

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FOREWORD

The Associate Chief of Staff for Research (ACOS) and the Research Administrative Officer (AO) are vital parts of a successful VA Research Enterprise. As the leaders for VA research at their respective facilities, they serve to ensure that science, administrative and policy requirements meet the highest standards as VA seeks to fulfill its research mission to our Veterans. Simply put, without the ACOS and AO, VA Research would not be possible.

This update of the Manual for Associate Chiefs of Staff and Research Administrative Officer reflects key changes in the organization, policies and procedures since ORD began its Research Enterprise Transformation efforts in 2020. The information provided aims to harmonize activities across Research and Development (R&D) Offices/programs to improve efficiencies in how research is conducted. Additionally, this update helps with better alignment of the various enterprise units involved in achieving important scientifically driven outcomes for Veterans and the nation.

The ability for VA Research to optimize its impact requires several elements working together and understanding their organizational context. The scientific, operational/administrative and policy requirements all need to function in a systematic way, considering VA operates the nation's largest integrated healthcare system. Additionally, the VA Central Office/Headquarters and field research units all have key responsibilities for carrying out a broad set of research activities that span many disciplines while also needing to consider other relevant clinical and operational/administrative partners. Guidance and tools such as ones contained in this Handbook will help with providing a basis for enabling continual improvement processes to meet future needs.

VA continues to support a highly robust intramural research program that blends the clinical care and educational activities as part of its statutory missions. Within VA, clinician scientists and non-clinician scientists seek new and innovative ways to improve clinical diagnoses and therapies that will benefit its Veteran patients. The VA research program focuses on addressing matters directly affecting Veterans, which the end results lead to the discovery of new medical knowledge and create innovations that advance the health and care of Veterans. In doing so, many of the discoveries made by VA researchers are further applicable to the population at large creating tremendous value for the nation. The impact of VA Research extends beyond the individual by improving system processes in care delivery, engaging communities, and helping demonstrate what a collective dedication to service through research can achieve. VA Research attracts and recruits the best and brightest clinicians and non-clinicians to its facilities and serves as a tool to retain these extraordinary individuals, as part of a commitment to high-quality, high-impact health care for Veterans.

Underlying the research itself, one of VA's greatest assets are the personnel who share in a commitment to serve Veterans and the nation. The individuals and teams who range from scientists, research personnel, administrators, budget/fiscal experts, regulatory/compliance staff, and other employees all make it possible to execute the research mission. The Office of Research and Development, within the Veterans Health Administration Central Office serves to provide the foundation for the work. However, the day-to-day responsibilities are carried out by the R&D Offices located at VA Medical Centers throughout the country. These groups have a major responsibility for the enterprise to help ensure investigators can perform their research – in the most supportive of an environment possible. It is why the ability for ACOSs and AOs to succeed is critical.

This Manual is dedicated to all in Research Administration, who are on the front lines as well as working behind-the-scenes to facilitate the VA Research Enterprise. This resource seeks to recognize the breadth and complexity of work involved while also serving as a primary tool for helping them succeed in their respective roles.

"BECAUSE OF YOU, IT WORKS!"

Grant Huang, MPH, PhD
Deputy Chief R&D Officer – Enterprise Optimization

Special thanks to all who have and continue to work on this manual (the initial version dates back to 2012).
Final thanks to Gery Schulteis and Kari Points for their many long hours in updating this version.

INTRODUCTION

Research Administration in VA continues to evolve since the version of the AO Guide was compiled and published in 2012. It is still a fact that in VA Research programs around the country, no two Associate Chiefs of Staff for Research (ACOS) or Administrative Officers (AO) do the same things from one facility to the next. However, as the Office of Research and Development (ORD) moves to an enterprise system and the communication between programs strengthen, we have ongoing opportunities to share knowledge to increase efficiencies in managing our programs. For that reason, we continue to update this ***ACOS/AO Manual*** which provides a practical source of information for those who oversee VA research administration at the local level.

Due to the positive reception of the last version, this version of the manual has been updated based on the number of changes that have occurred in the last several years. We expect that the document will continue to evolve in the coming years but hope that with the new additions, it will continue to be a resource for ACOSs, AOs, and other involved in managing VA Research.

ACRONYMS

A VA document would not be complete without a listing of acronyms. Here are a few more common ones. For more, this tool helps in finding other ones in VA: VA Glossary - Power Apps

14RD	Office of Research and Development
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AAHRPP	Association for the Accreditation of Human Research Protection Programs
ACES	Attendance and Cost Estimation System – (VHA External Conference Request System)
ACORP	Animal Component of Research Protocol
ACOS	Associate Chief of Staff
ADO	Associate Directors Operations (NODES)
AMP	Actively Managed Portfolio
AO	Administrative Officer
AWE	Annual Workplace Evaluation
BBMH	Brain, Behavioral and Mental Health
BLR&D	Biomedical Laboratory Research and Development (legacy Service, retired under ISRM)
CDW	Corporate Data Warehouse
CFR	Code of Federal Regulations
CID	Commons ID
CITI	Collaborative Institutional Training Initiative – (training modules for various research topics)
COI	Conflict of Interest
COR	Contracting Officer's Representative
COTR	Contracting Officer Technical Representative
CPRS	Computerized Patient Record System
CRADA	Cooperative Research and Development Agreement
CRADO	Chief Research and Development Officer
CSP	Cooperative Studies Program
CSR&D	Clinical Science Research and Development (legacy Service, retired under ISRM)
CVMO	Central Office Veterinary Medical Officer

DMAP	Data Management and Access Plan
DO	Director Operations (Director, Research Operations)
DoD	Department of Defense
DSMB	Data and Safety Monitoring Board
DUA	Data Use Agreement
EPA	Environmental Protection Agency
ePROMISe	Enterprise Project Management Information System
ePROS	Enterprise Protections, Regulatory, Outreach, and Systems
eRA	Electronic Research Administration – National Institutes of Health
EST	Ethics Specialty Team
FACA	Federal Advisory Committee Act
FCOI-A	Financial Conflict of Interest Administrator
FDA	Food and Drug Administration
FDS	Federal Service Desk
FERSS	Field Enterprise Research Support Services
FRAC	Field Research Advisory Committee
FWA	Federal-wide Assurance
GAO	Government Accountability Office
GenISIS	Genomic Information System for Integrative Science
GOVTA	Government Time and Attendance System
HIPAA	Health Insurance Portability and Accountability Act
HR	Human Resources
HRPP	Human Subjects Research Protection Program
HSR	Health Systems Research
HSR&D	Health Services Research and Development (legacy service, retired under ISRM)
HST&C	Human Subjects Training and Credentialing
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
ICF	Informed Consent Form

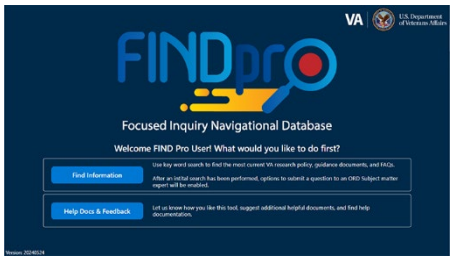
IG	Inspector General
IIR	Investigator-Initiated Research
IO	Institutional Official
IPA	Intergovernmental Personnel Agreement
IRB	Institutional Review Board
ISRM	Investigator and Scientific Review Management
ISSO	Information System Security Officer
ITA	Initial Target Allowance
ITOC	Information Technology Oversight and Compliance
JIT	Just in Time
LAMb	Laboratory Animal Major Equipment
LOI	Letter of Intent
MedHealth	Medical Health
MOU	Memorandum of Understanding
MSI-RSTP	Minority Serving Institution – Research Scientist Training Program
MVP	Million Veteran Program
NIH	National Institutes of Health
NIHMS	National Institutes of Health Manuscript Submission System
NOA	Notice of Award
NPC	Nonprofit Corporation
NLM	National Library of Medicine
NODES	Network of Dedicated Enrollment Sites
NPPO	Nonprofit Program Office
NRAC	National Research Advisory Council
OGC	Office of General Council
OIG	Office of Inspector General
OI&T	Office of Information and Technology
OMB	Office of Management and Budget
OPM	Office of Personnel Management

ORD	Office of Research and Development
ORO	Office of Research Oversight
ORR	Office of Research Reviews
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PACER	Program Assistance Consultation and Education Review
PACT	Patient Aligned Care Team
PBM	Pharmacy Benefits Management
PCS	Patient Care Services
PMC	PubMed Central – Archive of the NIH National Library of Medicine
PO	Privacy Officer
QuERI	Quality Enhancement Research Initiative
RAFT	Research Analysis Forecasting Tool
RCO	Research Compliance Officer
RCS	Records Control Schedule
RDCC	Research and Development Computing Center
RDT	Rehabilitation Research and Development and Translation
REQUIP	Research Equipment Quick Use Initiative Program
RIO	Research Integrity Officer
RISP	Research Information Security Program
RR&D	Rehabilitation Research and Development (legacy Service, retired under ISRM)
SAM	System for Award Management
SMRB	Scientific Merit Review Board
ShEEP	Shared Equipment Evaluation Program
SO	Signing Official
SORN	System of Records Notice
SRS	Subcommittee on Research Safety
STAR	Specialty Team Advising Research
TDA	Transfer of Disbursing Authority

TMS	Talent Management System – (Training modules in VA Learning University)
TTP	Technology Transfer Program
UEI	Unique Entity ID
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VAIRRS	VA Innovation and Research Review System
VERA	Veterans Equitable Resource Allocation
VHA	Veterans Health Administration
VINCI	VA Informatics and Computing Infrastructure
VistA	Veterans Health Information Systems and Technology Architecture
VISN	Veterans Integrated Service Network
VPN	Virtual Private Network
VMU	Veterinary Medical Unit
VSSC	VHA Support Service Center
WOC	Without Compensation

FINDING HELP

The ORD webpage has a large amount of useful information, FAQs, templates, etc. A good place to start is the resources link: Resources and Links (va.gov)



- The number one tool to find anything related to policy is the Focused Inquiry Navigational Database – FindPRO . This tool that aims to aid in finding information regarding ORD policy related to human, animal, and laboratory research protections.
- "**Policies and Guidance**" tab leads to important information on policies relevant to the administration of research.
- "**Programs**" tab has information on the variety of programs ORD offers.
- "**About Us**" has contact information for ORD. It also has a nationwide directory of ACOS, AO, and other field research office staff. You can search by name or by site.
- There are *listserv* groups that allow you to ask you colleagues for advice/help
    - AOs = vha14RDResearchAO2@va.gov
    - ACOS = vha14RDResearch ACOS2@va.gov
    - Both *listservs* are monitored by staff in ORD. Contact vha14RDAction@va.gov to be added to these listservs.

- **VHA Office of Research and Development ACOS and AO Mentoring Programs**: The Office of Research and Development (ORD) recognizes the complexities of running a research program, no matter the size. Associate Chiefs of Staff, Research Program Coordinators and Administrative Officers are expected to have a broad range of skills sets and knowledge on a myriad of topics. ORD has developed a program that focuses on advising on how to address many of the issues that research offices deal with on a day-to-day basis. The Mentoring program was developed in collaboration with field- based personnel to provide education, training, and mentorship to research administrators in the VA's intramural research program. The goal of the Research Mentoring Program will be accomplished in three parts: 1) provision of a manual for AOs and ACOS that can be used as a guide to basic operations of field VA research administration; 2) individualized training, mentoring, and guidance; 3) a continuing education program to outline changes in VA policies and directives that affect research operations and disseminate best practices and workable solutions to issues and problems faced in VA research administration. The program is designed to be customized to each facility requesting assistance. At the request of the facility Director, Chief of Staff, ACOS or AO, the mentoring team will address focused or broad areas. Ultimately, the goal is to develop a network and relationships where programs can rely on each other for expertise, guidance, and assistance. Should a mentoring visit be the best mechanism of assisting a Research Office, contact VHA ACOSRMentorCoordination@va.gov.

- **PACER:** ORD has developed a Program Assistance Consultation and Education Review (PACER) to bring expertise regarding research administrative matters to the site. The PACER is a 2.5-day visit at the request of the Medical Center Director and covers a variety of areas from space to regulatory issues. For further information contact the Director, Field Operations.

- **The Administrative Officer Council:** A group of Administrative Officers, representing a variety of programs, provides advice guidance and assistance to Field Operations. Matters discussed range from training to impact of policies on the research programs. They also serve as mentors to new administrative officers.

- **The ACOS Council:** A group of ACOSs, representing a variety of programs, provides guidance

and operational support to Field Operations with a specific emphasis on the ACOS role. Many members also serve as mentors to new ACOSs.

VA and VHA Handbooks and Directives

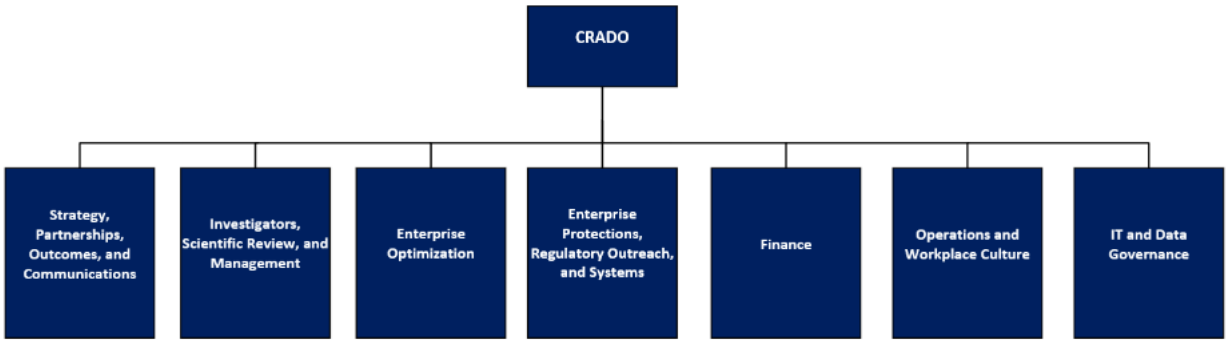
- Guidelines, policies, and regulations for VA research are encoded in a series of documents that include Directives/Handbooks and program guides.
- Directives related to Research start with the digits 120X.XX for ORD and 1058.XX for ORO.
- To access these documents, you can:
    - Use FindPro
    - Go to Program Guides, VHA Directive and Handbooks -- 1200 series (va.gov).

PLEASE NOTE: URLs beginning with www.va are Internet sites (accessible from any internet connected device). URLS with vaww.va are Intranet sites (only accessible from within the VA firewall).

ORD RESEARCH – Office of Research & Development

An Overview of the Organization and Structure of ORD

The Office of Research and Development (ORD) (14RD), in the VA Central Office, is part of the Veterans Health Administration (VHA). The other parts of the Department of Veterans Affairs are the Veterans Benefits Administration (VBA) and National Cemetery Administration (NCA). The leader of ORD is the Chief Research and Development Officer, or CRADO. Established in 1947, this Congressionally- mandated research program is unique among other Federal research programs in several ways: 1) It is focused entirely on Veterans' needs; 2) It is an intramural research program (i.e., only VA employees are eligible to conduct VA research); and 3) It is the only Federally funded research program that is directly tied to a fully integrated health care system. The mission of VA Research is four-fold: 1) to improve Veterans' health and well-being via basic, translational, clinical, health services, and rehabilitative research; 2) to apply scientific knowledge to develop effective and innovative individualized care solutions for Veterans; 3) to attract, train, and retain the highest-caliber investigators, and nurture their development as leaders in their fields; and 4) to assure a culture of professionalism, collaboration, accountability, and the highest regard for research volunteers' safety and privacy that ensures partnered information flow to and advance care for Veterans – and for all those who rely on the VA health care system.



Currently, ORD, under Investigators and Scientific Review Management Service (ISRM), supports research in biomedical laboratory, Medical Health (MedHealth), Health Services Research (HSR), Brain Behavior and Mental Health (BBMH), and Rehabilitation Development & Translation (RDT). The broad range of activities support pre-clinical research to understand life processes from the molecular, genomic, and physiological level in regard to diseases affecting Veterans to clinical trials and other research to determine the feasibility or effectiveness of new treatments (e.g., drugs and devices), compare existing therapies, and improve clinical practice and care. In addition, ORD funds research to develop novel approaches to restore Veterans with traumatic amputation, central nervous system injuries, loss of sight or hearing, or other physical and cognitive impairment to full and productive lives. Part of the overall program funds research at the interface of health care systems, patients, and outcomes examining all aspects of VA health care (e.g., quality, access, patient outcomes, and costs) including the VA Quality Enhancement Research Initiative (QuERI) to continuously improve VA health care by systematically implementing clinical research findings and evidence-based recommendations into routine clinical practice. Under Enterprise Optimization, the Cooperative Studies Program (CSP) is ORD's flagship clinical research enterprise division specializing in multisite clinical trials and epidemiological research on health issues of vital importance to Veterans. The Million Veteran Program (MVP) is ORD's most recent group that focuses on genomic research and maintains a national infrastructure for biospecimens, data and analysis. Both CSP and MVP coordinate closely with the ORD ISRM portfolios on conducting highly innovative approaches to addressing problems for the VA

healthcare system and nation.

In addition to these Portfolios and Programs, there are other crosscutting programs within ORD (see VA ORD Programs). These include the Biosafety and Biosecurity Program, the Animal Research Program, the Gulf War Program, the Biorepository Brain Bank Program, the Office of Enterprise Protections, Regulatory, Outreach and Systems (ePROS). A newly created division under Enterprise Optimization is the Partnered Research Program which facilitates external (e.g., with industry) partnerships with particular emphases on multi-site clinical trials involving the VA non-profit corporations. There is also a liaison office in ORD with the Department of Defense and other Federal governmental agencies that perform research (e.g., the National Institutes of Health and the National Science Foundation). The VA's Technology Transfer Program is also housed in ORD, as is the VA Non-Profit Program Office.

As part of the recent transformation, ORD created the ORD Operations and Workplace Culture (OWC) Section. OWC is responsible for mission and enterprise essential services for ORD including cultivating employee engagement, coordinating, and processing external requests and requirements, and managing day-to-day operations. Among the services OWC provides for ORD are managing all human resources needs, including hiring, timekeeping, promotion criteria, Diversity, Equity, and Inclusion, etc.; promoting employee engagement and wellness; overseeing and supervising ORD contracts; conducting Quality Assurance across ORD, and providing administrative support for research-related advisory committees. OWC is also the communication portal through which requests from external stakeholders are coordinated, monitored, and tracked including Congressional inquiries and requests from other external stakeholders.

Another section created as part of the reorganization, the Strategy, Partnership, Outcomes, and Communications (SPOC) unit serves as the cornerstone of the Office of Research and Development (ORD), crafting and stewarding ORD's forward-looking strategy towards achieving its mission. By anticipating the evolving landscape of science, biomedical research, and the unique needs of Veterans alongside healthcare priorities, SPOC ensures that VA Research remains relevant and a trailblazer in delivering unparalleled value to Veterans, the VA itself, and the nation at large. In support of this strategy, SPOC fosters robust engagement and long-term relationships with a vast network of partner organizations, stakeholders, and professional associations. Through these endeavors, SPOC guarantees an efficient and unified approach to community building. SPOC also articulately communicates and showcases ORD's work. It adeptly translates complex scientific successes into compelling narratives that resonate across diverse audiences. In doing so, SPOC highlights ORD's contributions and fortifies its position as a leader in advancing healthcare for our nation's Veterans.

ORD also has sections that are involved in overall finance and budget matters affecting all R&D services and ORD, including human resources, bioinformatics, information security, and the central clearinghouse for inquiries directed to ORD from the Secretary and Under Secretary, Deputy Under Secretary for Health for Policy and Services, other offices within VA, private organizations, and additional *too- numerous-to-count* entities.

ORD interfaces with many parts of VA Central Office, but two partners are particularly important:

Office of Research Oversight (ORO) ensures the responsible conduct of VA research. ORO provides oversight of compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. ORO also provides training to facility Research Compliance Officers (RCO) and oversight of RCO auditing programs.

Office of Academic Affiliations (OAA) oversees VA's teaching mission, its training programs, and its

affiliations with academic institutions.

Field Research Advisory Committee

In 2003, the Deputy Undersecretary for Health determined that the establishment of the Field Research Advisory Committee (FRAC) was in the best interest of the VA research program. The purpose of the Department of Veterans Affairs FRAC is to promote communication between ORD, Research Offices, and investigators in the field, provide input and advice on issues relevant to VA research including current operations, and participate in strategic planning. Membership is comprised of both VA Central Office and field staff. More information can be found at https://www.research.va.gov/resources/frac/default.cfm

National Research Advisory Council

The Council provides advice to the Secretary and the Undersecretary for Health (USH) and makes recommendations on the nature and scope of research and development sponsored and/or conducted by VHA to include: 1) the policies and projects of ORD; 2) the focus of research on the high priority health care needs of Veterans; 3) the balance of basic, applied, and outcomes research; 4) the scientific merit review process; 5) the appropriate mechanisms by which ORD can leverage its resources to enhance the research financial base; 6) the rapid response to changing healthcare needs, while maintaining the stability of the research infrastructure; and 7) the protection of human subjects in research. More information can be found at https://www.va.gov/advisory/nrac.asp

Field Research Program Leadership

The core leadership team of all field-level research programs is comprised of the Associate Chief of Staff for R&D (ACOS) and the Administrative Officer for R&D (AO-R). While many programs, especially larger ones, may have one or more Deputy ACOS, and/or a Director of Research Operations, the minimum requirements per VHA Directive for all research programs is an ACOS and an AO-R. As shown in the Key Relationships diagram, these positions are a central point of interface within the medical center chain of command, with ORD, and with partners such as the local VA non-profit corporation (NPC, see Section 16) and/or the academic affiliate (see Section 15). At the local facility, the ACOS reports to the Chief of Staff.

The ACOS is the Service Chief for Research Service, and this is generally a full-time position that is paid from Medical Care funds. The ACOS can be either a clinician or non-clinician PhD. Per VHA Directive 1200.02 *Research Business Operations* a minimum of 5/8ths time must be dedicated by the ACOS to administrative oversight of the research program; any time dedicated to the ACOS's own independent program of research must be IN ADDITION to the 5/8ths time devoted to program administration.

For some large research programs, there are ORD-funded centers or Centers funded by national clinical programs (e.g., Mental Health [MIRECC], or Geriatrics [GRECC]), as well as collaborations with different program offices such as Rural Health, that support the research program and further enhance the complexity of operations overseen by the ACOS and AO-R. No matter whether there are 10 projects or 500 projects, the number of collaborative programs or partners, and the size of the research program support team, the ACOS and AO-R must have a fundamental understanding of all aspects of research management, and this manual serves to collect the required core knowledge, with links to additional resources to expand when and where needed.

The ACOS and AO-R have varying responsibilities assigned to them under VHA Directives and Program Guides, and a comprehensive listing of these responsibilities extracted from the various Directives/Guides can be found in Section 29. You may find this list useful as a quick reference guide, and while these responsibilities are critical, do NOT assume from the extensive list that the positions of ACOS and AO-R are merely "pre-scripted routines" to be executed with limited room to exercise strategic planning, ingenuity, creativity, and persuasion. To the contrary, as detailed below it is exactly THESE types of attributes that promote success in leading a VA research program.

THE ASSOCIATE CHIEF OF STAFF, RESEARCH & DEVELOPMENT

The role of the VA Associate Chief of Staff for Research and Development (ACOS) is to **Build** and **Sustain** a **Creative, Collaborative** and **Compliant** research program. While there is no better start than an ACOS being a successful researcher, let's consider some of other crucial skills and attributes for success in building and sustaining an innovative research program:

Build: The ACOS leads efforts to build the research program by helping in recruitment of researchers, strengthening existing programs, and developing new programs. This requires knowledge of the existing researchers, the clinical and education needs of the Medical Center and the areas of research focus of the VA, the NIH, the DOD, and other funding organizations. To achieve this, the ACOS needs to work with VA Clinical Section and Service Chiefs, facility Executive Leadership (most notably the Chief of Staff and Medical Center Director), Department Chairs & Deans at the affiliate university, and NPC leadership. Outstanding communication, negotiation, and persuasion skills therefore are critical to success. Recognizing, recruiting, retaining, and supporting a talented team of administrative support staff, starting with the AO-R, is also critical, and becomes increasingly important as the program grows.

Sustain: Sustainment is not a passive process but an active one that aids the present and assures the future. Roles for the ACOS include facilitating recruitment of junior investigators to groups, helping investigators and groups find new resources to build and create an atmosphere that keeps investigators at the VA. The knowledge base and local working partners are the similar as for Build, but also includes working with facility support services such as Engineering, Logistics, IT, and others to ensure resource and infrastructure support commensurate with the size and scope of the program.

Creative: To build and sustain a great program, the ACOS must recognize and promote creativity in research investigators and programs. The ACOS has to see the potential and develop it. It is especially important to see the potential in new recruits and to help them blossom. This may involve creating mentoring programs, using knowledge of research to link researchers to relevant fields & programs and to encourage researchers to pursue novel ideas. In addition, the ACOS must frequently apply creative thinking in helping new and established investigators alike navigate bureaucratic requirements as efficiently as possible while maintaining compliance, so that the primary focus is on innovative research and not regulatory burden.

Collaborative: Research is increasingly collaborative, but researchers are often in silos. The ACOS has indispensable knowledge of the local researchers and programs, so is in the ideal position to promote collaboration. The ACOS needs to be informed of and serve as a connection to regional and national partners. The ACOS can help create (and participate in) seminars, works-in-progress groups, and other groups to promote their types of collaborative research.

Compliant: Compliance with regulations is necessary but compliance oversight processes are often viewed as obstructions by researchers. The ACOS should lead by example and create an atmosphere and culture in which ethics and compliance are embraced through education and viewed as an essential element of the research process to ensure safety, integrity, and validity/reliability of the data. By working to make compliance a collegial partnership with oversight entities, whether local, regional, or national (see Section 13 for details), the ACOS can play a crucial role in making compliance easier and facilitating good working relationships between regulators and researchers.

THE ADMINISTRATIVE OFFICER

Administrative Officers/Directors of Research Operations (AO-R/DRO) come in all shapes, sizes, ages, and experiences. But the role from site to site shares some common characteristics. They are:

Organized: In all cases, an AO-R needs to be able to be very organized and have systems in place to track the myriad of tasks that need to be performed.

Connected. In talking to AO-Rs from around the country, one of the things heard most of the time is: **you do not need to have all the answers, but you do want to know who to contact regarding the questions that come up.** AO-Rs work closely with committees, staff, researchers, and a variety of service lines within the Medical Center to build consensus and create collective solutions. Forming excellent working relationships with key individuals in other Medical Center Services goes a long way to being successful in furthering the Research Mission. Sometimes those key individuals are not the Service Chiefs, but front-line individuals who are facile in the actual day-to-day tasks.

Attentive: Many AO-Rs are very good at attending to details, while being able to keep the bigger picture in mind. These are individuals who can listen to the complaints or suggestions of a mega-funded researcher, or a staff member, with equal focus.

Creative: AO-Rs must often work with diverse groups and individuals and come up with unusual solutions. They often need to think "outside the box" to find that new understanding of an issue that no one had before. Be open to networking and consulting with other AO's whether it be a mentor, another AO in your VISN, someone you met at a conference or through the AO list serv. If you are stuck, reach out to a fellow AO and brainstorm with them. They may have had the situation before or have an idea to help you reach a solution.

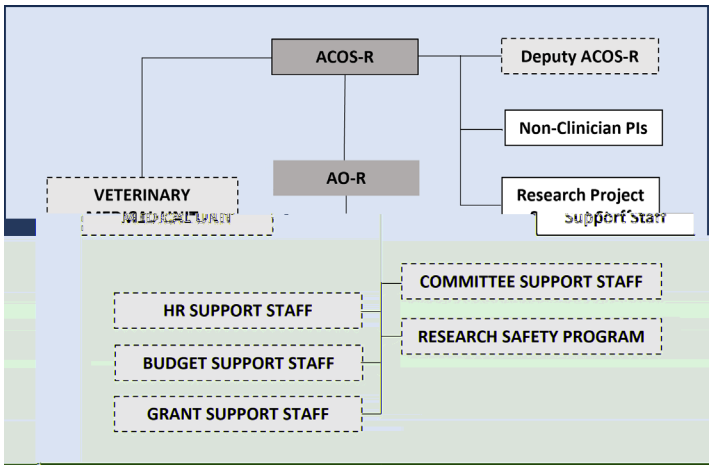
Reasonable: We live in a world of regulations. You, ORO, accrediting organizations, and ORD may have differing opinions on the correct interpretation of the regulations. You can be paralyzed by this situation, or you can adopt a reasonable attitude and pursue the course of action that makes the most sense to your group of decision-makers.

Patient: Most everyone you will work with is juggling multiple tasks (including yourself). You may have to be patient before getting a response needed to resolve an issue.

Informed: As stagnant as people believe the government to be, its environment is in constant change. Inform yourself as much as possible about new regulations, changes in staffing at your immediate facility, changes in ORD funding focuses, key initiatives being pursued at your facility, as well as changes going on at the affiliate university. As mentioned above, become familiar with whom to contact when issues or questions arise.

THE SUPPORT TEAM FOR THE ACOS and AO-R

As noted in the sample Org Chart, the ACOS supervises the AO-R (or Director of Research Operations [DRO], if appointed), and as applicable a Deputy ACOS (if appointed), the Veterinary Medical Officer (for stations with an animal research program), and non-clinician Research Scientists (unless a Deputy ACOS is designated as supervisor). While clinician scientists are directly supervised within their clinical service units, the ACOS can be viewed as a "dotted line" supervisor of their research functions. Because Principal Investigators (PIs) are not typically coded as supervisors, the ACOS (and/or Deputy ACOS) may also be the formal supervisor of record for the research project support staff (although technical training and day-to-day direction of research activities are overseen by the PI and/or other senior project staff).



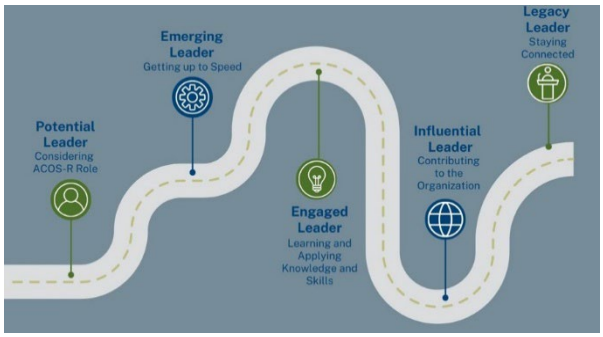
Depending on program size and complexity, other staff may provide support for research staffing/ appointments, budgets/contracting, intramural funding submissions, committee support, and more, and these administrative support positions are typically supervised by the AO-R.

The most obvious reason for the differentiation in staffing support at different facilities is the number of projects, types of funding, and types of research (human, animal, bench, informatics/analytics) conducted by the center's research program. At some smaller facilities, the AO-R may serve as a "master of all trades" as there are limited resources for support staff. However, in larger programs the AO-R/DRO serves as the conductor of an extremely diverse orchestra.

Capturing All the Research Enterprise Has to Offer

To realize the ultimate potential of everything the Research Enterprise has to offer, we can all benefit from each other's experiences, seeking to replicate successes and learning from challenges to turn an initial "No" into a "Yes".

Tremendous and varied knowledge and expertise exist within the ACOS and AO-R/DRO community. The community members are willing to share their expertise and want to learn from others who have been down similar roads. This gives the opportunity for grassroots learning, creating a rich and meaningful, just-in-time, research-leader-specific support, and training experience. Accordingly, we encourage the newer members of our community to take advantage of the resources available on their journey from Potential to Emerging to Engaged Leader. This manual serves as a core guide, but tremendous additional support is available in the growing ORD Suite of Services for Field Research Leadership Development, and many of these resources are linked in this manual. The ORD-led ACOS/AO Mentorship Program and PACER visits, described in more detail elsewhere (Section Finding Help), are excellent tools to learn from established experts in our community. Finally, we encourage those who have been Engaged Leaders for some time already to take the next step in the journey to Influential Leader and impart your expertise for the benefit of newer community members, perhaps joining the ACOS/AO Mentorship Program, which enriches the Enterprise as a whole.



SECTION 1 – Basic Information

What is Research?

The VA defines research as: a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute information to the generalizable knowledge of a scientific discipline (or other scholarly field of study). A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. The VA definition of research is consistent with the Office for Human Research Protections (OHRP). VA research is defined as "research that is conducted by VA Investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated."

As was taught in high school, research begins with a hypothesis – a statement that explains or makes a generalization about a set of facts or principles, usually forming a basis for possible experiments to confirm its viability.

All research is driven by a **protocol**. A protocol describes the exact process to be undertaken for the research study. The final results of research protocols are **data** and the **analysis** of that data. In a business sense, the "deliverable" of a research study is its data. A protocol should be written in enough detail so that a scientist or researcher can read it, follow it, perform it, and arrive at similar data as anyone else. This data can be analyzed to make conclusions. The "power" of the data is driven by its statistical significance which is driven by the quantity and variability of the data. Statisticians help researchers understand how much data to acquire for their study to have statistical significance.

Why Does the VA have a Research Program?

Research is vital to providing the best care to our nation's Veterans and has been codified as one of the four main missions of the VHA. Research accomplishes this mission directly through the advancement of science and knowledge and indirectly by attracting healthcare providers who have an interest in being part of leading- and cutting-edge medicine.

Congress has recognized the importance of VA Research by allocating a designated source of money to be used for the support of VA research, i.e., the VA Research Appropriation.

As noted in an excerpt from "VA Research: Improving Veterans' Lives – A Historical Look", published in 2010:

"While the evolution of federal programs for the delivery of post-service care to Veterans is well charted, the point at which medical research became an important consideration is less defined. No direct act of the legislative or executive branches of government dictated that Veterans' health care could be enhanced with a research component. The association of research and clinical care grew mainly from the wisdom and foresight of medical practitioners themselves. Records from early meetings of advisors and consultants charged with addressing large-scale medical needs among Veterans after World War I reveal gathering convictions that research could and should be integrated into Veterans' health care. Beyond the positive benefit of relating that research to the unique medical circumstances of Veterans, the move was received as key to reinforcing an evolving system of care. Many of these advisors felt that making the system attractive to physicians with research interests and cultivating

relationships with medical education institutions would ensure the highest quality of care to Veterans."

"In 1924 and 1925, a Medical Council was established to consider issues of care for Veterans within the Veterans' Bureau. This council wrestled with the notion of research investigation in the context of Veteran care and ultimately endorsed the idea unanimously and the first Research Chief was hired. Since the beginning, the research emphasis has been on how best to help Veterans and not on pure academic advancement of knowledge. In the beginning, studies had no specific funding, or were funded from the investigator's own resources. The first centrally funded research came in 1933, for a cancer research lab at the Hines VA Hospital in Chicago.

"World War II put VA research in a kind of hibernation, but post WWII launched the modern era of the VA. In 1947, affiliations with medical schools took effect. The NIH began its grants program in 1945. Despite difficulties within hospitals about how to integrate research, by 1952 the VA had medical research programs at 66 hospitals with 373 employees paid from money set aside for research generating over 800 research publications. In 1953, Research became a healthcare service on its own. From 1954 to 1959, the research budget grew almost fourfold. Research within the VA was to continue to grow and diversify into its [current] system."

Published in June 2011, this article gives the accounts of VA Physicians, who are involved in research, and claim to have a higher rate of job satisfaction.

In 2020, VA Research observed 95 years of advancing science at the VA through research.

VA ORD supports just approximately 2,500 research projects nationwide, ranging from preclinical studies to health services research, to multisite clinical trials.

The types of research that ORD supports include:

- Investigator-initiated research (Merit Review)
- Mentored research (Career Development)
- Large-scale, multisite clinical trials (Cooperative Studies Program)
- Research Centers
- Service-Directed Research

- Utilizing the academic affiliate or NPC, researchers at VAMCs are also eligible to apply for extramural funding from other sources such as NIH, DoD, or industry sponsors. In1988 Congress passed legislation that empowered VAMCs to establish VA-affiliated nonprofit corporations (NPC). The legislation enabled the establishment of private, state-incorporated NPCs that provide a flexible funding mechanism for the administration of non-VA funded research. Additional information on NPCs can be found in Section 16: Non-Profit Corporations.

  The total amount of resources dedicated to VA Research from all sources is over $2 billion. For current information regarding the budget you can go to VA Budget Products.

Managing and Growing a Research Program

Engaging in research and being successful in it is a challenge in the current climate of limited funding resources with more competition for funding. To be successful, one of the tenets seems to be that successful funding for the lone investigator is declining and that collaborative research with the contribution of multiple investigators, each lending their expertise to a specific aspect of the proposed research, appears to now be the more accepted model. In this fashion, enlisting the assistance of those who have cutting-edge technologies or methodologies or who can bridge the translational research gap will greatly aid a research project. In VA Research, having a translational model even with basic science research, or performing clinically relevant research addressing a Veteran- centric need, are important components of a successful application for funding.

To enable the growth of a research program at the facility level, a critical mass of talented and vibrant investigators is needed. This can be accomplished by having a balanced spectrum of: 1) well-seasoned senior investigators who are good not only in their science but in mentoring younger investigators; 2) mid-career investigators who will in the coming years fill the role of senior investigators and are developing their skill in mentoring and networking; and 3) junior investigators who are starting their research careers and need the encouragement, guidance, and infrastructure to maintain their passion for science and not be discouraged by the difficult funding climate.

Growing such a balanced research program requires the efforts and commitment not only the ACOS, but a close partnership with Clinical Service Chiefs who can identify and recruit talented clinician-scientists at all levels (senior, mid-career, and junior) committed to building a career at the VA. It is critical that the ACOS consider meeting routinely with the Clinical Service Chief in recruitment efforts for new clinical faculty that may want to establish a research program in the VA. The ACOS would be able to emphasize the necessity for research benefiting Veterans as Veteran-centric type research may be more competitive for Merit Review Award applications. In planning a new clinician recruitment, the Clinical Service Chief would also benefit from the ACOS's insight into the potential research contributions and accompanying protected effort based on the types of awards the prospective recruit is eligible for and likely to secure. A joint effort with the Department Chair at the affiliate, and the nonprofit corporation (NPC), is also helpful to assemble the resources needed to recruit and retain top-notch scientists at all levels within the joint VA/university/NPC environment. Moreover, it is critical that VA facility Executive Leadership provide a supporting environment for the conduct of research through research time mapping in DSS commensurate with the contributions to Research VERA made by a given investigator's funded VA-based research program. In summary, a committed team of VA facility Research Service, VA Executive Leadership, VA Clinical leadership, and affiliated NPC and university Departmental Leadership work together to grow and maintain a healthy research program.

As growing a research program implies bringing in more funded investigators, making investigators aware of VA as well as non-VA Requests for Proposals or other funding opportunities is a critical role that the ACOS should play. The ACOS should be familiar with the current portfolio of the Research Service, and the strengths of the investigators so when appropriate funding opportunities or a call for proposals comes up, those opportunities can be brought to the attention of specific investigators. Suggesting or nominating an investigator to assist on a VA Review Board may help the investigator learn about the VA peer review process and how the Board approaches the evaluation of an award submission. Thus, an investigator who understands what a Board looks for in various types of submissions (basic, translational, clinical, career development, etc.) can probably use that knowledge for his or her own future applications, and mentor other younger VA investigators on the process. In addition, by fully understanding the scope of the VA and affiliate research program and the investigator roster at both, an ACOS can serve as a facilitator of collaboration, to assist investigators in establishing the necessary interactive research proposals that are increasingly the model of choice of major funding agencies, including NIH and VA intramural research.

Attracting Experienced Scientists

Attracting senior and mid-level scientists with substantial funding and resources may be challenging, particularly in the VA environment where the "start-up" packages typical in academia cannot be provided, and collaboration with the affiliate is indispensable in these recruitments. For starting investigators, the VA's Career Development Program is an effective mechanism that would allow them up to 6/8th protected time (or 8/8th for non-clinician) to develop an independent research program after the conclusion of the award.

For clinician-investigators at all levels (early, mid, and senior), clinical needs of the Medical Center and

the desire to pursue a research career in the VA by the recruit could be facilitated using VA FTEE. In conjunction with the Clinical Service Chief and with the approval of the Chief of Staff, a part-time VA FTEE could be offered to the recruit. A 5/8 VA FTEE would allow for the clinician-scientist recruit to be automatically eligible to apply for VA funding and not need to go through the 8th's waiver process. This offer of VA clinical FTEE is often an attractive incentive that the VA can contribute to the joint recruitment process.

For non-clinician scientists, entry into the VA's intramural research program can be by the Career Development route if the non-clinician scientist is no more than 5 years out of completion of the PhD degree at the time of submitting their CDA-2 initial pre-application (or 2 years post-PhD for a CDA-1). For non-clinician scientists who are not already funded VA investigators and do not qualify for the Career Development application, a pre-application review to the Portfolio of interest (Medical Health (MedHealth), Brain Behavioral & Mental Health (BBMH), Health Systems Research (HSR), Rehabilitation R&D and Translation (RRDT), or Actively Managed Portfolios (AMP)) is required, as it is for all applications (See Section 5 for more information). An accepted pre-application makes the non-clinician scientist eligible to submit the full application, and if funded they remain eligible during their period of funding to submit additional new applications (each investigator can hold up to 3 Merits at any one time). For renewal of an existing application for a non-clinician PI, their eligibility continues for up to 12 months after the lapse of their most recent intramural funding. While the Summer and Winter cycle review panels, which cover primarily the HSR and RDT portfolios, do not currently limit the number of NEW non-clinician investigators (those without funding as PI within past 12 months) that can submit to a given round, the Spring/Fall cycles which cover primarily the MedHealth and BBMH portfolios limit each station to ONE new non-clinician application per portfolio (1 MedHealth, 1 BBMH) in each round of review. Each portfolio (MedHealth, BBMH) also will consider up to ONE exception/waiver request per station each round. For those new non-clinician investigators responding to an AMP Notice of Scientific Interest (NOSI), the AMP Director can sponsor at their discretion the exception/waiver request if needed to ensure review of the additional application from your station in the Spring/Fall rounds. Once a new non-clinician has submitted their A0/initial application, the A1 and A2 applications are included and that individual no longer is considered "new" for those resubmission applications; therefore, each station will have up to ONE MedHealth and ONE BBMH new non-clinician slot each Spring/Fall round at minimum (with any additional subject to review and approval of an exception/waiver request).

Another critical contribution that VA facilities can often make to the recruitment process is research space which may be more available at the VA than at the academic affiliate. The availability of space may be an attractive means to recruit investigators (especially young investigators) to the VA and thus is one means to growing a research program. Working with the affiliate's Medical School Dean (perhaps even at the level of the Associate Dean for Research) to help identify investigators in need of research space can be helpful as well as advertising for clinician needs at the VA in conjunction with VA clinical Service Chiefs and the Chief of Staff.

Although the larger VA research programs may have research core facilities in place to serve the VA-based research community (and affiliate investigators as well through appropriate recharge mechanisms), many VA facilities with smaller research programs may have at best modest or no scientific core infrastructure support. In such cases affiliation with a well-established university usually offers an abundance of already established cores, such as Imaging, Morphology, Specialized Microscopy (confocal, atomic force microscopy, etc.), Biostatistics, Informatics, Sequencing – to name a few. For those VA investigators with dual appointments at the affiliate, securing the ability to utilize cores at affiliate recharge rates assists VA research programs that need specialized services not available at the VA.

To establish shared equipment and core facilities at the VA, space to house the core staff to run the

core, and for large equipment, service contracts, need to be fully considered. While the VA has the ShEEP and LAMb equipment programs for large multi-user and VMU equipment, respectively, those funds cover primarily the cost of major equipment, and finding funds to support personnel to run the core and/or obtain a service contract (usually 10% of the cost of the equipment) may be difficult. The VA NPCs may be of some assistance in these cases should there be sufficient funding from overheads taken in by the VANPs. Establishing recharge rates for shared equipment use run a core service type model may help recover such costs; other non- VA grants could potentially be of help in covering such costs.

Protected Time for Research and Relationship to VERA

VHA has issued guidance on the amount of protected time recommended for various research activities. See *VHA Directive* 1065. Included is a table that can be found at VA ORD Guidance for Protected Time for Research Staff

Research - Mapping Allocations Research Activity	Recommended FTEE Allocation	Recommended Hours per week
Principal Investigator (PI) Merit review incl. QUERI	0.380	15.2
Chair on VA Cooperative Studies Program (CSP)	0.500	20.0
Site PI on Merit/VA CSP	0.250	10.0
PI NIH ROI*	0.380	15.2
PI Industry-sponsored Clinical Study	0.250	10.0
VA Career Development Award (CDA)	0.750	30.0
Major Foundation Awards	0.250	10.0
PI of VA Center of Excellence	0.500	20.0
Mentor of VA CDA	0.060	2.4
New Investigator	0.500	20.0
Chair, Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)	0.500	20.0
Chair, Institutional Bio-safety Committee (IBC) / Subcommittee on Research Safety (SRS) or Research and Development Committee	0.130	5.2
Member, IRB, IACUC	0.130	5.2
Member, IBC/SRS, R&D Committee	0.060	2.4
Other Research duties not covered above approved by COS, i.e., (peer reviewer of manuscripts referred for abstracts, editor of book, monograph, or other publications)	0.025	1.0

The *above* table is only guidance, and each individual Medical Center may modify the suggested amounts of protected time in accordance with its needs. This protected time, or "mitigation time", is blended into the overall labor mapping for clinician investigators.

The Chief of Staff is responsible for staffing decisions for clinicians within the medical center. Input may be sought form the Research service regarding the amount of VERA research dollars generated by a given investigator's ongoing activities. An example is provided *below*.

An Example for VA Merit:

Dr. Doe: 8/8 VA MD clinician faculty with:

$220,000 salary + $65,000 benefits = total cost $285,000 per year.

Dr. Doe is the Principal Investigator of a VA Merit Award with budget of $165,000 per year x 4 years.

Issues to consider:
1. Dr. Doe needs protected time to conduct VA Merit-funded research. Based on the *VHA Handbook* 1065.01, Dr. Doe requests, through his section chief, 3/8 protected research time – equivalent to $82,500 salary + $24,400 benefit (total $106,900 per year).

2. As an MD faculty, Dr. Doe cannot put his/her salary on VA Merit Review (i.e., Dr. Doe's FTEE counts towards Medical Center FTEE with salary coming from the Medical Center).

3. VERA equivalent for $165,000 VA Merit: $165,000 x 100% x $0.65 (an average of recent VERA "national price") = $107,250 per year. The Medical Center will receive credit for $107,250 per year towards this study beginning in the second fiscal year after the start date (e.g., VERA in years 2026-2029 for a Merit funded 2024-2027).

4. The clinical service is recommended to protect 3/8 FTE (15 hours a week) for Dr. Doe and find someone who can provide coverage for this effort, or other arrangements made by the clinical service with current available faculty.

From this example, it is evident that Merits with a more limited budget (e.g., $165,000/yr.) may produce VERA that barely meets the cost of the protected time for the clinician. In other cases, larger Merit Award amounts ($300,000/yr.) will yield greater VERA (e.g., $195,000 using the example multiplier of 0.65 from recent averages), allowing for VERA income to appropriately cover research infrastructure costs in excess of the cost of the PI's protected time. In addition, consider that VERA generated from extramural awards may have no protected time cost at all, in cases where the PI is providing effort on the extramural award through outside compensation (e.g., affiliate university time). Finally, non-clinician PI awards yield as much VERA as the equivalent award to a clinician, but again come at no cost of protected time since the non-clinician draws salary directly from the award. In this fashion, a healthy research program with a blend of clinician and non-clinician PIs and extramural as well as intramural funding can cover protected time for the PI, as well as co-Investigator protected time, protected time for new investigators, and bridge support for PIs between awards, in addition to other appropriate VERA infrastructure costs.

Additional Considerations

The potential for protected research time (clinician PI) as compared to providing for one's own salary through Merit funds (non-clinician PI) should be discussed and planned *up front* when recruiting new investigators who wish to conduct research on VA time (whether starting with preparation of funding application or after funding award). Considerations to be covered in such a discussion would include:

Impacts of shift to VA employment, or dual employment by VA and affiliate: As described earlier, unless a waiver is granted, a minimum 5/8ths VA-paid appointment is required to accept a funded intramural award, and this will impact time commitment to the university faculty appointment. For faculty coming over to the VA from the affiliate, consideration should be given to comparators between affiliate and VA annual and sick leave differences, merit increases (as is the usual case, with the affiliate), differences in retirement programs, as well as differences in health benefits and/or other fringe benefits. Part-time appointments at the VA and the affiliate usually have benefits pro-rated according to the percentage of effort at each institution. Thus, the prospective faculty member or technical research staff (who are current affiliate employees) need to weigh in these differences prior to deciding on switching employment, dual employment, or remaining with their current employer (Note that reduction in benefits through a shift to dual employment is NOT an acceptable justification for a VA 8ths waiver).

Approval to submit funding application will need to include prior planning discussions with Service/Section Chiefs,

ACOS, COS, etc., with a plan for potential coverage if or when the clinician investigator is funded, as well as the duration of "protected time" provided for funding application – especially for new or early career faculty members.

VERA funding for the Medical Center will increase with additional funded studies that are approved by the local R&D Committee. There is not a mathematical relationship in protected time for research in this situation, which can vary for the individual investigator and the facility. Generally, the facility will set the maximum protected time allowed to any clinician or investigator. For example, if Dr. Doe has an additional NIH RO-1 funding ($250,000 per year) being conducted 50% at the VA, but administered by the university affiliate, this will result in additional VERA financing. Based on clinical, administrative, education, and research needs, this should result in further discussion between the investigator, ACOS, and the Medical Center, regarding the total protected time for research beyond the 3/8ths provided under Dr. Doe's Merit Award.

Growing a Program - Investigator Transfer

Programs can also grow by "inheriting" clinician or non-clinician investigators who move from another VA station. Reasons for a move may be personal/family or in many instances, a VA investigator may be recruited by another academic institution and that new academic institution has a VA affiliate. The Investigator seeking to move to a new VA who would like to take his/her VA award(s) to the new VA should first call the ACOS at the proposed new VA to explain the reasons for the potential move and the feasibility that the Investigator could be accommodated at the new facility. Considerations include available research space of the appropriate type, equipment needed (if VA equipment or other non-VA purchased equipment cannot be moved from the current VA or academic affiliate), potential VA collaborators and other needed resources such as animal facilities, relevant patient population, etc. available at the new VA so that the current ongoing research can successfully continue at the new site. Consultation with the ORD Program Officer early in the process is also encouraged to ensure that any ORD criteria for approving the ultimate transfer can be discussed with the new facility. Especially for clinician-scientists, discussion with the new VA Clinical Service Chief and Chief of Staff should be done early in the process to see if VA FTEE are available that would be critical to ensuring a smoother transition and to meet the VA FTEE requirements for sustaining VA funding. Additionally, administrative personnel in the new clinical service could begin the process of onboarding with local Human Resources. Once the groundwork has been successfully set for transfer to the new VA and the current VA Research Office has been notified of the impending transfer, the ORD Project Modification (ProjectModification.pdf) can be completed and sent in to ORD for review of the potential transfer. The modification request is formally submitted by the original VA at which the award was first made, but the new station ACOS and Research Office can provide critical information and support to successful completion of the modification request. Once approved for transfer by ORD, the Investigator should secure the necessary paperwork or access to the new site's electronic project submission and review process to obtain the new site's research committee and subcommittee approvals. Special consideration should be given to human subject projects when PIs propose to transfer. The wording on informed consents and other documents may dictate the ability to transfer data to the new site.

VA funding transfer to the new site should be handled by the fiscal officers of the respective ORD Portfolio that is funding the research. However, should the Investigator have funds at the current VA NPC or university affiliate, this requires additional negotiations with the individual sponsor(s) of the funding, and the institution currently administering the award(s). For instance, for CRADAs involving funds administered by the current VA NPC corporation, a new CRADA would need to be established between the new VA NPC/Medical Center and the company partner; this may require OGC review to establish the new CRADA. Movement of funds from the VA NPC for other investigator-initiated research would need to be approved by the funding agency (e.g., if source of funding is from a private foundation or other non-VA governmental entity) and agreement by the administering NPC to relinquish the award. Some completed studies that may have "left-over" funding that the funding organization did not want returned, are usually kept in a "various donors" type of account at the VA NPC. This funding may be at the discretion of the Board of Directors of the VA NPC whether it would be relinquished to the new VA NPC; similar funding transfer issues at the university affiliate may also arise. In addition, movement of

affiliate- or NPC- purchased equipment would be at the discretion of the current owner as to whether to relinquish equipment to the new site.

In many instances, it is up to the transferring Investigator to secure the funding for the actual move. Occasionally, the receiving university affiliate may fund the move as part of the recruitment package. Payment by VA for relocations are generally limited to new employees to Federal service. Guidance on the rules for relocation expense coverage can be found under VA Financial Policy, Volume XIV, Chapter.

Prior to arriving at the new site, the Investigator would need to complete the hiring process, security clearance and new badging if necessary and be put into the VA PAID system at the new VA through Human Resources/Financial Management. IT transfer of VA data files, e-mails, etc., would also need to be done but the receiving Research Office and/or Clinical Service may have specific contacts in the IT Service that can assist with this. Transfer of VA-owned equipment can be coordinated through the respective Logistics Service of the prior and new VA Station once a new EIL is established at the receiving station for the transferred VA equipment.

Growing a Program – Career Development Award

While VA research has been one of the shining highlights and a best kept secret in VA, a real jewel of the VA's intramural research program is its Career Development Award (CDA) Program. This program is open to clinicians and non-clinicians and is an entry point into VA research. The applicant does not have to have prior VA 8ths (VA FTEE) to enter the program, but should the application be successful, would need to follow the table below when appointed.

	CDA-1	CDA-2	MSI -RSTP
Clinician Salary	9 Calendar month plus 2/8^{ths} from VAMC	6-9 Calendar month plus 2/8^{ths} from VAMC	6-9 Calendar month plus 2/8^{ths} from VAMC
Non-Clinician Salary	7.5-12 calendar months	7.5-12 calendar months	7.5-12 calendar months
Project funds	See RFA	$75K/yr	See RFA
Award Duration	Up to 2 years	3-5 Years	CDA-1: Up to 2 years (Some Services) CDA-2: 3-5 years
Eligibility	Max of **2 years** beyond completion of training	Max of **5 years** beyond completion of training	Same as CDA 1 or 2 plus mentors at both MSI and VA

For clinician applicants, discussion amongst the prospective applicant, clinical service chief, COS, and ACOS is critical to ensure that the clinical FTEE commitment to the applicant is feasible, as well as any clinical back-fill if the applicant has a current clinical load exceeding the 8ths allocated during the CDA. Since the bulk of salary for the CDA would come from Research Appropriation and salary payment can come from only one source, often the CDA is costed to the research appropriation and then 2/8 clinical time and dollars are expense transferred from Research Service to the medical care appropriation. However, this can complicate transitions to and from the clinical appointment at the beginning and end of the CDA, as a clinician's appointment must be switched from clinical to research back to clinical, and therefore a number of programs now establish and maintain the appointment in the clinical service throughout the CDA, with cost transfer of 6/8th expenses to the research appropriation, thereby maintaining one appointment in the clinical service consistently before, during, and after the CDA award. Salary support for the CDA is generally up to 5 years (for CDA-2) and up to 2 years for CDA-1. For the CDA-2 level, there is $75,000 in research funding provided in addition to the PI salary support, to help support study expenses and a research coordinator or lab technician (for a CDA-1 this is limited to $20,000 per year in

addition to PI salary). Always refer to the RFA for specific guidance on current criteria for 8ths and allowed budget amounts as these may change. Applications for all types of CDAs require a Letter of Intent (LOI). The eligibility requirement pertaining to application for a CDA-2 for a clinician is that at the time of LOI submission and approval the clinician must be no more than 10 years out of receiving his or her clinical degree, and no more than 5 years out of completion of their last clinical training. For a non-clinician applicant, the applicant should not be more than 5 years out of completion of their terminal degree (e.g., PhD) at time of LOI submission. At the CDA-1 level the eligibility requirement is that the applicant is no more than 2 years out of clinical training, or if a non-clinician, no more than 2 years out of their terminal degree. In addition, a CDA applicant must be a United States citizen.

The primary mentor of the CDA applicant should be a VA Investigator with current Merit Award funding. Other co-mentors as appropriate to mentor the CDA in specific scientific knowledge, skills and techniques, or other aspects of career development, can be from the university affiliate, another VA, or other non-VA institution.

ORD also has the Minority Serving Institution -Research Scientist Training Program (MSI-RSTP) award which is an evolution of the Historically Black Colleges and Universities Career Development award, expanding the minority research training program to other types of Minority Serving institutions (MSI) as defined in US federal statute under the Higher Education Act (HEA). Department of Education among others maintains a listing of MSIs. Most MSIs qualify for federal funding based on annual undergraduate or graduate enrollment of minorities and graduation criteria (such as Hispanic-Serving Institutions (HSIs), Predominantly Black Institutions (PBIs), Native American Serving Nontribal Institutions (NASNTIs), Alaska Native and Native Hawaiian Serving Institutions (ANNHIs), and Asian American and Pacific Islander Serving Institutions (AANAPISIs)), while two types are statutorily defined: Historically Black Colleges and Universities (HBCUs) and Tribal Colleges and Universities (TCUs). The intent is to bring an early career CDA at a minority serving institution (like Morehouse) into the VA system where they work with a VA Mentor on their CDA.

The ACOS is responsible for monitoring the overall progress of the CDA and must provide an annual letter of evaluation at time of RPPR submission.

Once the CDA is completed, clinician-investigators are expected to return to their clinical service, and there is an expectation that the VA facility maintains at least a 5/8ths appointment to maintain the investigator's eligibility for Merit funding. With successful Merit funding, the recommended protected time (see table) of 3/8ths to complete the Merit research should be provided. On occasion, a clinician investigator may not successfully secure independent Merit Award funding by the conclusion of the CDA; in this case a CDA Transition Program could be developed whereby Research Service could negotiate with facility leadership for a bridge funding program that provides continued support of at least 5/8ths, with some of it protected to allow time for continuation of the research program, publication of CDA results, and continued application for Merit funding for a period of time (e.g. 1-3 years). This use of Research VERA funds for promising investigators needing some additional support time in transition to independence can be a critical investment in future growth of the Research Program, and in turn additional Research VERA.

Career Development Enhancement Award (CDEA)

The CDEA award is for senior investigators and is an intramural funding mechanism designed to support established funded VA Merit Review researchers to pursue creative, innovative, and impactful research activities and/or to acquire specific skills that will significantly augment the investigator's research program and enhance the scope of VA research. Salary support can be up to 6 months at a 50% basis. Approval is needed from the local Medical Center, especially if more than 50% effort is requested.

Considerations for Small and Medium-Sized Programs

A critical component to program growth is getting the Medical Center and VISN Leadership buy-in for the program. Communicate often - keep leadership involved every step of the way.

You need to understand the culture at your medical center. You must have dialogue between your office and the potential researchers in your medical center. Many times, leadership wants a research program and wants it to grow, but they don't fully understand the impact that it will have on workload for providers and other key medical center staff. There needs to be a level of commitment from these key clinical areas such as medicine, surgery, and pharmacy. These areas are typically where the impact of research will be felt (i.e., protected research time). Chiefs of these services need to be able to plan for clinical metrics and distribution of workload. While the promise of future Research VERA growth to help support clinician protected time and other necessary research infrastructure support costs can and should be discussed, it needs to be clear that a commitment of resources at the beginning is going to be necessary, with a substantial lead time before significant Research VERA recovery can expect to cover all necessary research support costs.

Space is another area of concern within most medical centers. Are there any dedicated wet labs, animal facilities, or will it only be a clinical research program? An inventory of both space and equipment available needs to be assessed. Can some clinical used equipment such as imaging (MRI, PET, CAT), deep cold freezers, and centrifuges be shared with research? How about clinical staff assisting in areas such as phlebotomy or imaging?

Ability to attract clinicians with a demonstrated track record of, or potential to develop, an independent program of research can also be difficult at sites that have not previously had a robust research program. For those programs affiliated with a university that has an established robust research program, engaging in joint recruitment as described earlier can potentially be a fruitful way to incrementally establish a research program at the VA facility while relying upon shared faculty and resources of the affiliate.

Some small- and even medium-sized research programs may not currently have an academic affiliate. Growing the research program in an environment without a developed affiliate with a robust research program of its own creates additional hurdles to overcome, as recruitment of research-minded investigators to an isolated VA without direct academic affiliate presents significant challenges. In such cases, an additional strategy involves looking to other research programs within the VISN to see if a partnership can be forged with another program. Such bonding could be accomplished through a sharing of research space, expertise, or research committee work (e.g., reliance of the smaller program on the IRB, IACUC, Safety, and/or R&D Committees of the larger program). While physical distance between Medical Centers could be a hurdle, the use of electronic protocol submission and review processes as well as other tele- and video- communications facilitators may help to alleviate some of the logistical problems. By using a single IRB for both sites, this can help the smaller program grow by enabling its clinician investigators to join as a potential additional recruitment site to a study already in place, or being submitted for funding, at the larger facility. In this fashion, investigators with a more limited research portfolio at the smaller program can develop their research portfolio over time through collaboration, and ultimately transition to independence, helping the program grow its base of independent investigators.

Once you have a plan and goal for your medical center, and the required commitment from facility leadership and any necessary support from the affiliate, set up your Gantt chart or task list in a way that makes the most sense. The list of tasks can seem daunting. However, setting realistic goals and setting sensible benchmarks will help you to focus your energy.

SECTION 2 – Getting a Research Project Approved

How to Determine If a Project Meets the Definition of VA Research

What is VA Research? VA research is research that is conducted by VA investigators – serving on compensated, without compensation (WOC), or Intergovernmental Personnel Act (IPA) appointments – while on VA time and/or in VA space (owned or leased). The research may be funded by the VA, by other sponsors, or be unfunded. All VA research must receive initial approval from the local Research and Development R&D Committee.

Who Can Be a VA Investigator?

A VA investigator is any individual who conducts research approved by the R&D Committee while acting under a VA appointment on VA time, including full and part-time compensated employees, WOC employees, and individuals appointed or detailed to VA under the IPA of 1970. (***NOTE:*** *Individuals working under a contract with VA or on a fee-for-service basis cannot be given a WOC appointment to conduct research. Contractors and those under fee-for-service can provide clinical service or other activities in support of VA research in accordance with their contract or agreement. Trainees (e.g., students, residents, or fellows of any profession) may serve as participants, but not PIs within a VA facility.*

The Process to Become a VA Investigator

Some VAMCs have a formal process for designating individuals who are eligible to be PIs. This might include an interview with the ACOS and/or a review of the investigator's experience and training. If indicated, the ACOS or R&D Committee may stipulate that the investigator work with a mentor while they gain the necessary experience. In most cases, a prospective clinical investigator must first be granted research time by his or her Service Chief and/or their Chief of Staff for appropriate labor mapping.

Principal Investigator Orientation

Orientation by the ACOS and/or other members of the Research Administration staff on various aspects of project submission, compliance matters, securing research space, infrastructure support for Information Security, how to hire staff, how to order, how to manage finances (research budgeting), among other items goes a long way to setting a new or even "old" PI in the right direction to enable their program to run as efficiently and effectively as possible. Meeting individually with PIs has the advantage of imparting information to the investigator either early in their research career in the VA, or upon entering the VA, and enables the orientation to be individualized to the type of research in which the PI may be involved. Occasionally, having group meetings with PIs or "town halls" to go over new policy or updated procedures that have come down from ORD or ORO or new local Medical Center procedures are helpful to impart such information to the broad base of PIs.

A myriad of topics can be covered, but project submission, applying for VA funding and the nuances of the VA intramural research program are important subjects to go over. Potential sources of funding, both VA and non-VA, potential collaborators who may be doing similar types of work at the Medical

Center can be discussed. It is also helpful to go over topics such as:

- the VA NPCs and any rules for administration of non-VA funded projects.
- intellectual property and the role of the VA and university affiliate in intellectual property for dual appointees.
- requirements for data and information security in the VA, training requirements of PIs and staff who are engaged in research.
- procedures of who, when or what to notify for publication of manuscripts, abstract presentation, or media contact.
- The unique nature of VA intramural funding and need to expend funds within a fiscal year with no more than ORD-approved allowance for carryover of funds across fiscal years,
- VA travel requirements and procedures.
- VA time and attendance policies and procedures; and
- VA research equipment custodial requirements and expectations.

In addition to these topics, a listing of who are good points of contact in research administration in addition to the ACOS and AO who may be of assistance in project submission, safety issues, interaction with support services is also an excellent piece of orientation material. An item that should be discussed with PIs is that governance of the R&D Program at the local level is a partnership between Research Administration and the R&D Committee. PIs make up all or the majority of the voting members of the R&D Committee and are an integral part in ensuring that the research program is fully functioning and progressing. Thus, committee service on the various VA research committees should be broached with the PI as a part of their commitment to ensure the success of the research program and their responsibility to other PIs at their Medical Center.

There may be different ways to document the orientation meeting. For instance, it may be required that an Assurance document be executed outlining general PI responsibilities and more specific one for those who perform human research versus those performing animal or basic science research.
An example can be found at https://www.research.va.gov/resources/policies/guidance/form-investigator-assurance.doc

Additionally, a memo to the new PI can be generated, outlining responsibilities of being a PI. An example can be found at https://www.research.va.gov/resources/policies/guidance/generic-VA-paid.doc

Securing Approval to Conduct VA Research

1. ***To initiate a project, contact the Research Office***

   The Research Office can point the PI in the correct direction as to what items must be submitted for review and to which of the research committees would need to perform the review of the research project. Some projects may not meet the definition of research and may be considered quality assurance / quality improvement (QA/QI) projects. A great tool to utilize in determining if a project is Research or QA/QI is the VA Electronic Determination Aid (VAEDA). Additional information on what may be considered QA/QI can be found in Program Guide: VHA Operations Activities that May Constitute Research – 1200.21.

2. ***What subcommittee approvals are needed for the proposed project****?*

   The R&D Committee acts as a "Board of Directors" or governance committee for the Research Service. Part of this role includes providing oversight of internal VA subcommittees as well as providing final determination on all initial project submissions. The subcommittees the R&D

Committee oversees may include your in-house (or other VA) IACUC, IRB, SRS, and IBC. As part of this oversight, the R&DC is charged with reviewing the committees annually to ensure they have the needed support, membership, and resources to conduct and complete committee work. The R&DC also has final determination of all initial submissions from both the in-house (or other VA) subcommittees listed previously, as well as all initial submissions to external committees of record, which might include your affiliate IRB, commercial IRBs, or other federal IRBs, external IACUC, and external IBC. Project submissions to any of the subcommittees (in-house, other VA, or external IRBs) can be initiated simultaneously, but all relevant subcommittee approvals must be obtained before R&D Committee approval is obtained.

a. **Subcommittee for Research Safety (SRS)** – This subcommittee reviews and approves protocols for work conducted in wet lab space within the research footprint, work with hazardous agents or other safety issues that are being conducted at the VA.
   i. Duties of the SRS are covered in VHA Directive 1200.08(1) "Safety of Personnel and Security of Laboratories Involved in VA Research".
   ii. For those who are uncertain about what the project requires, contact the AO, SRS Chair, or Research Biosafety Officer, if the facility has one, for clarification.
   iii. When using Recombinant DNA, Institutional Biosafety Committee (IBC) approval prior to commencing work is required. Contact the SRS chair for more information.

b. **Institutional Animal Care and Use Committee (IACUC) –** This committee must approve all projects involving experiments with animals.
   i. VHA Directive 1200.07 "Use of Animal in Research" is the relevant policy dictating animal work in VA.
   ii. VAMCs may have their own IACUCs or use an affiliated university's IACUC through an MOU.
   iii. All protocols must have a veterinary consultation prior to review by the IACUC. Location and funding of animal work will dictate what animal committee and form is used to obtain approval. The submission, regardless of what form/committee, should include a memo with responses to the veterinarian consultation.
   iv. Projects that are funded by the VA Research Appropriation must be reviewed by the VA IACUC of record, regardless of where the studies will be performed, and use the VA Animal Component of Research Project (ACORP) forms. In rare cases, the Affiliate animal protocol form will be accepted, but this must be discussed with the Research Office and IACUC Chair prior to submission. Generally, an MOU between the VA and the Affiliate outlines reciprocity and acceptable reviews should be put in place to formalize the protocol review process between institutions.
   v. Projects considered VA research and funded by sources other than VA or VA NPC where procedures are performed at the Affiliate may be reviewed by the Affiliate IACUC and accepted by VA as outlined in the MOU noted in ii above. Care should be taken to ensure that this is VA Research.

c. **Institutional Review Board (IRB)** – all studies involving human subjects, or the use of identified human samples or data, must be reviewed by the IRB of record identified for that project.
   i. VHA Directive 1200.05 "Requirements for the Protection of Human Subjects in Research" is the relevant Directive.
   ii. The facility's IRB(s) of Record may include the facility's own IRB(s), the VA Central IRB, an IRB of another VA facility, the IRB(s) of its affiliated medical or dental school, or an IRB of another federal agency or a commercial IRB (e.g., Western IRB, Advarra, Sterling, etc.), through an MOU or Reliance Agreement (see ePROS Single IRB web page: IRB

Relationships in the VA: Single IRB Exceptions, Independent (Commercial) IRBs, and changing IRB reliance by the VA Facility for more information).

iii. All projects must be reviewed by the PO and ISSO.

iv. The VA Central IRB reviews multisite projects. Typically, these are funded by VA and involve several (e.g., >3) sites. The scope of the Central IRB is expanding to include multisite industry-sponsored trials. The Central IRB can advise whether a protocol is appropriate for submission for review. In Central IRB submissions, one site is the PI or Study Chair, and they coordinate the submissions from the local site investigators. Information on the Central IRB is located under the heading for ORPP&E, or the Program for Research Integrity Development and Education. https://www.research.va.gov/vacentralirb/default.cfm.

d. Exemption Subcommittee – all studies determined to be exempt from human subjects oversight. Due to the implementation of the 2018 revised common rule, facilities have the option of creating a new subcommittee whose sole purpose is to review exempt studies.

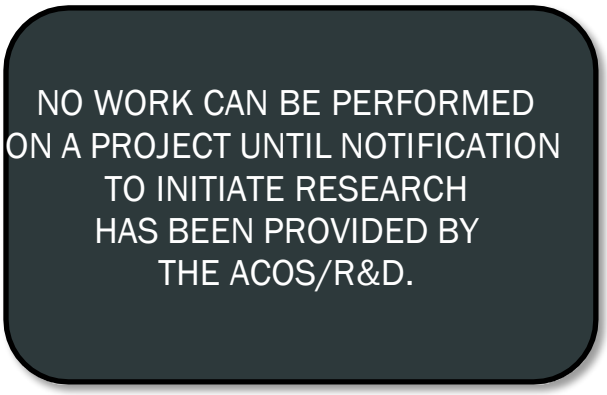
i. VHA Directive 1200.05 and 1200.01 "Research and Development Committee" are the relevant directives.

ii. If a facility does not have an Exemption Subcommittee, then an IRB member must first determine the study is exempt before the project is reviewed and overseen by the R&D Committee. An IRB member will need to review the project any time an amendment/modification is submitted to ensure the project still meets the definition of exempt, prior to the R&D Committee reviewing the request.

iii. If a facility has an Exemption Subcommittee, the subcommittee is the oversight committee of record and will conduct reviews of the initial submission as well as all modifications/amendments.

3. R&D Approval

ALL relevant subcommittee and R&D Committee approvals must be obtained before the ACOS can notify the investigator that a new project can commence. The R&D Committee will notify the ACOS that a project has secured all applicable subcommittee approvals, as well as R&D Committee approval, which allows the project to be initiated.



Protocol submission to the Research Office. New projects are submitted in the VA Innovation and Research Review System (VAIRRS). Every new project is required to complete the Project Cover Sheet Wizard, Study Team Tracking Sheet Wizard, and for those that will include human subjects, the IRB Information Sheet Wizard. Additional required forms are determined by the type of project. In addition to the required forms, the study team may be required to upload copies of any of the following forms: budget, proposal (grant, science portion), assessment of

clinical impact, "Biosafety" approvals, and external IRB approvals. Human subjects protocols would include additional forms, such as informed consent, HIPAA authorization/revocation, as well as others based on what is involved in the study (e.g., drugs, devices, etc.). Two additional documents are required in VAIRRS to assist the Information System Security Officer and Privacy Officer with their reviews. For all projects, study teams will need to complete and upload the Enterprise Research Data Security Plan (EDRSP) for the Information System Security Officer review. For projects that include human subjects, study teams will complete the 10-250 and upload it along with their study documents for Privacy Officer review. The plan is to develop these two documents into Wizards within VAIRRS for study teams to populate and attach to their submissions, until then the stand-alone documents must be downloaded, populated, and attached to the submissions as appropriate.

Conflicts of Interest. Consideration must be given to financial conflicts of interest specifically to receiving outside compensation and representations of an investigators outside employer (university or NPC). Prior the ACOS releasing the project to commence, these issues must be addressed. Further information can be found in VHA Directive 1200.13 and the Outside Compensation web page.

Required Training to Perform Research at the VA

There are specific training requirements for various research categories that must be satisfied before research personnel (including the PI, co-investigators, technicians, coordinators, etc.) can begin work on a VA research project, and periodic refresher requirements that vary according to the training category. The Research Office will help determine what trainings are necessary. More specific courses of various research training can be found in Section 9.

Quality Improvement/Quality Assurance Tool (VAEDA).

The VA Electronic Determination Aid (VAEDA) is a decision support tool that provides a *preliminary* determination. It was created to:

1. **Improve standardization** in regulatory preliminary determinations for proposed research, quality improvement, program evaluation, and innovation projects
2. **Reduce** administrative burden on research offices and IRB members
3. **Decrease** regulatory risk to the Agency
4. **The VAEDA tool harmonizes and standardizes project classifications (research/not research) for all VA facilities.**

NOTE: Research studies that are known to need an IRB review (clinical trial) or involve animals (IACUC review) do not need to go through the VAEDA process.
VAEDA Tool: https://vhacdwdwhvda01.vha.med.va.gov/vaeda/home#/
VAEDA Site Admin Request Form: https://forms.office.com/g/FXT4g6tYVr
VAEDA Homepage: https://www.research.va.gov/programs/orppe/vaeda.cfm
VA Electronic Determination Aid (VAEDA) Cyberseminar Overview:
https://www.research.va.gov/programs/orppe/education/webinars/session_archive.cfm?RecordID=206910&Date09212022

SECTION 3 – Finance Background

Money comes in different "buckets" for research. For example, there are administrative funds for the administration of the research program such as Cost Center (CC) 101. There are program (award) funds in support of the funded research projects awarded to your facility's investigators. There are other funding buckets that will be described in a later section of this chapter.
The program funds described below are Congressionally appropriated VA R&D funds, allocated by ORD:

Program	Description
820	ORD
821	BLR&D
822	RR&D
824	HSR&D
825	Cooperative Studies Program (CSP)
826	Million Veteran Program (MVP)
829	CSR&D

VHA also receives congressional appropriations to support Medical Care, and these may support the research enterprise in a more global sense (i.e., not for specific projects). For example, Medical Care dollars support the salaries of VA clinicians during their protected time for conducting VA research. Monies cannot be moved from one appropriation to another without Congressional approval. Subcategories of Medical appropriations include: 0160 for Medical Services; 0152 for Medical Support and Compliance; and 0162 for Medical Facilities.

While monies cannot be moved from one appropriation to another, expenses can be moved through a cost transfer. Cost transfers between the Research appropriation and the Medical Center appropriation typically occur for salary costs. While less frequent, there may be a time when the Medical Center and Research share the costs of a purchase order. When planning on moving costs between appropriations, a Memorandum of Understanding (MOU) should be in place detailing the costs that are being reimbursed.

There are certain awards that ORD will send out funds for in the Medical Care appropriation. These funds include the Toxic Exposure Fund (TEF), QUERI and Program 870. These funds need to be managed by the Research Office and follow the guidance regarding cost transfers between the appropriations.

Managing Research Funding

First and foremost, and it cannot be understated – **SPEND YOUR MONEY**!

Too often research programs wait too late to start urging investigators to spend the money they have on

hand. To the best of your ability stay on top of your budget and continually work to reduce the amount of last-minute spending. ORD now requires quarterly expenditure reports to be entered in RAFT after Quarter 2, Quarter 3, and Quarter 4 to ensure projects remain on track for spending during the fiscal year. ORD will set a specific percentage each quarter that project expenditures should be at. Projects not meeting the specified threshold are required to enter comments detailing the reason the project did not execute the funds. This emphasizes the need to manage your funds and communicate with PI's early in the year to develop spend plans.

The Government Fiscal Year begins on October 1 and ends on September 30.

Spend your PRIOR YEAR (PY) money first and by the deadline set by ORD. As you know, Research receives two-year monies, and it is important to use up your Prior Year funds first. Prior Year funds should be spent down utilizing cost transfers for salaries from Current Year (CY) to Prior Year. They should not be used for new obligations, credit card orders, etc.

While Research receives two-year funds, it is important to limit the amount of carry-over into the 2nd year. ORD annually sets the carry- over amount that needs to be met. Sites over the carry-over amount will either have funding reduced by that amount in the next year or have those funds pulled. Guidance will be provided by ORD each year on carry-over limit and how the overage will be handled.

Advise ORD early of any unspent money.

If you are not going to use the money sent to you by ORD, let ORD know as soon as possible. That way ORD can make sure that it gets spent. If the money lapses (goes unspent), it makes it very difficult to get the same amount of money (or more!) the next year from the Congress.

1. Look in the VSSC website under the finance tab at your Status of Allowance (daily report showing ceilings, obligation totals and balances by ACC code) and F20D (daily activity report) reports *daily (located at https://vssc.med.va.gov)*. More information on the VSSC later in this section.
2. Develop a good relationship with your Fiscal Office and CFO.
3. **Do not over-obligate your First Quarter distribution when operating in a Continuing Resolution.** (This can become *tricky* when working with contracts based on a 12-month scope of work.)

Types of Money

Cost Center 101 (CC101) Funds

A portion of the VA ORD annual budget is allocated to support the administration of the research program at each VA facility with a research program. Research administration activities typically include personnel for research administration, supplies, or other types of broad research support (not relegated to any specific research project). The intent of CC101 funds is to supplement the overall support from the facility and to ensure that the Research Office has the personnel resources and adequate staffing to support the overall program. – CC101 funds are allocated to the Research Service *only*.

The formula changed for FY 23 and has several components associated with the program including types of committees, number of projects by type, VA funding, number of VA submissions to grants.gov, and number of projects.

The total CC101 distributed will be limited to an amount budgeted and approved by the CRADO. The

current year CC 101 funding amount for a particular station may vary but the intent is to not be less than 80% of the CC 101 of the previous FY. The amount of 101 funds that are provided to a station, or withheld from a station, may be based on the ability of a station to execute its budget – that is to be sure that prior year (PY) funds are expended or obligated without any significant outstanding balances.

Award Funds

Project Awards come from the Office of Research and Development programs. These funds are directly tied to a specific award and are intended to be used by the principal investigator (PI) designated in the proposal. If a project is delayed or if expenditures vary substantially, the PI is required to either return the unused funds or file a project modification plan (PMO) with the funding entity and gain their official, written approval of how funds can be used alternatively or have an extension of the project to utilize funds in the future. Information on submitting a project modification form can be found at: https://www.research.va.gov/resources/policies/general_admin.cfm.

Veterans Equitable Resource Allocation (VERA) Funds

VERA dollars are allocated annually to VA medical centers and hospitals to support their operations, including medical and personnel expenditures. The amount of VERA dollars received is directly tied to the type(s) of patient care provided by the facility, the number of Veterans it serves, the number of unique Veteran patients seen, the complexity of patient medical problems, medical procedures performed, and other factors. Education contributes to the VERA based on the number of trainees that a Medical Center trains. VAMCs also receive VERA funds in proportion to the amount of research ongoing at that site. Research support is a separate and distinct component of VERA because research programs vary substantially across Networks and medical centers.

The total amount of Research VERA dollars available for distribution each year is fixed by VHA Finance. To determine each VAMC's share, the quantity of their research allocations (VA) and expenditures (non-VA) is tabulated through the RDIS report (see below). The amount is calculated as follows:

Type	*Administered by*	*Amount*	*Discount Rate*	*VERA $**	*=*	*Calculated VERA*
VA merit award	VA	$150,000.00	**100%**	0.65	=	**$97,500**
DoD Grant	NPC	$250,000.00	**100%**	0.65	=	**$162,500.00**
NIH Grant	Affiliate	$250,000.00	**75%**	0.65	=	**$121,875.00**
Industry	Affiliate	$100,000.00	**25%**	0.65	=	**$16,250.00**
** VERA $ Rate changes annually and is determined by VHA Finance*						

1) Funds administered by the VAMC (which is VA funding) and funds from peer-reviewed sources (e.g., NIH, DOD, etc.) as well as non-peer-reviewed source (e.g., pharmaceutical companies) administered by the VA-NPCs count at 100%. Note that some types of VA Medical Care funds, such as QUERI/870 funding, is also counted as VA research dollars (100%) in the VERA calculation.
2) Funds from peer-reviewed grant administered by the academic affiliate are discounted by 25%, so you only count 75% of that total.
3) Funds from non-peer-reviewed sources administered by the academic affiliate (e.g., industry-sponsored awards) are discounted by 75%, so you only count 25% of that total.
4) The adjusted or discounted amounts are tabulated for each VAMC.
5) The total amounts for all the VAMCs are summed.
6) The amount available for Research VERA is divided by the total reported expenditures in the system to get the National Price for Research Support. For example, if the total adjusted research expenditures across the US is $1 Billion million and the available VERA dollars are $650 million, then the National Price is 65.0% - each VAMC gets 65 cents for every dollar of adjusted research allocations or expenditures reported in RDIS. ***Please note that the VERA National Price percent changes each fiscal year.***

7) Detailed information on the VERA calculation is available at http://vaww.arc.med.va.gov/references/faqs/faqs/faq_tt.html
8) To see how much VERA Research support has been allocated to your site go to http://vaww.arc.med.va.gov/. Click the link for the most recent VERA Final Reports in the upper right of the page. The Research VERA is listed as Table 7, and at the bottom of that page, you can also find archived reports from previous years.
9) Note that it takes two years to transform reported research expenditures into VERA dollars, so the amount distributed in 2024 is based on 2022 RDIS reports.
10) Note also that unfunded projects do not generate any VERA funds, but still require the resources of the Research Office in terms of compliance and assurance.

The Research and Development Information System (RDIS) mechanism used by VA research programs to report annual research expenditures across the research program, including intra- and extramurally funded projects led by VA investigators at the facility, is the source that determines the facility's research contribution to VERA. (See **Systems** for a detailed description of RDIS.) Accurate RDIS reporting by the facility Research Office for total expenditures on each grant, award, or agreement (pharmaceutical and biotech trials) in the Electronic Project Management and Information System (ePROMISe) is essential to ensuring an appropriate VERA research support allocation. Allegations of over-reporting expenditures to increase VERA research support are investigated by the Office of the Inspector General. Under-reporting expenditures will decrease the VERA allocation for research support at your facility. (Keep in mind: The expenditures from the previous 2 years determine the current year VERA allocation for research support.)

VERA research support is disbursed at the VISN level; distribution of VERA research support at the facility level is at the discretion of the VISN Director. While some VISN Directors keep the VERA research support at the VISN to support research needs benefiting the entire VISN, many distribute the VERA research support to the medical centers within the VISN based on their respective contributions to the total research support allocation. This portion of the allocation is to be used at the Medical Center Director's discretion but should be used to benefit research by supporting infrastructure for the research program. The appropriation language from Congress is that the VERA allocation is *"For necessary expenses in the administration of the medical, hospital, nursing home, domiciliary, construction, supply and research activities..."* One useful rule of thumb to remember is that the research VERA allocation is to be used for items that benefit the research program as a whole – for example, the IRB or HRPP program. Note that a large portion of research VERA dollars are used to cover the salary of clinicians during the protected time that they use to conduct VA research. ORD does not pay the salaries of clinician-investigators working on VA-funded research – this is the responsibility of the VA Medical Center. So, to function properly, the research service needs the support of medical care, administrative, and facilities resources at the local level. These include housekeeping, IT equipment (PCs, network, printers, and telephones), engineering support (HVAC, power, minor repairs, etc.), administrative staff (HR and Fiscal), protected time for physician and other title 38 employees, etc. Unlike extramural awards administered by the VA NPC or academic affiliate, VA intramural research awards do not come with so-called in-direct costs attached to each award. Rather, infrastructure support from the facility is intended to be covered by the Research VERA allocation, which is awarded to each station in proportion to their funded projects. However, it is not uncommon to encounter questions from medical center leadership and support services on what is administrative and compliance in nature versus what is in support of a specific research study or set of studies. Consequently, at some facilities it can be difficult to get consistent support for research administration furniture, copy machines, and other items. If you run into this issue, seek guidance from the network (VISN), or from other VA facilities, and bring that information to the attention of your fiscal officer and Associate Director.

VistA (Veterans Health Information Systems and Technology Architecture) is an enterprise-wide information system built around an Electronic Health Record (EHR), used through the Veterans Health Administration (VHA). It is a collection of about 100 integrated software modules. It also contains the Integrated Funds Distribution, Control Point Activity, Accounting and Procurement (IFCAP/VISTA), which contains a large portion of the financial system used throughout the VHA. Orders are normally placed in IFCAP/VISTA and balances for each fund control point (FCP) are tracked using the FCP official menu. It is important to have appropriate access to this system.

FMS (Financial Management System) is the VHA general ledger, the primary repository of VA financial data. It categorizes spending by fiscal period, station, and account. Both labor and non-labor spending are reported. FMS reports are available in the VSSC – https://vssc.med.va.gov. The current list of FMS subaccount codes, also called Budget Object Codes (BOC), is available by searching *VA's Financial Policy*

VSSC (VHA Support Service Center) – https://vssc.med.va.gov. The VSSC website is available to anyone with VA network access and contains valuable FMS reports that are read only. Several reports can be obtained from the VSSC that assist in managing overall balances in the fund control point. These include the F20 - Daily Activity by Account Classification Code, the Status of Allowance (SOA) and the FMS OBLL – Open Obligation reports. These all can be found in the Finance section under the Facility Administration section of the VSSC.

- F20 - Daily Activity by Account Classification Code – Provides a list of all FMS activity by ACC codes for a select period of time in the fiscal year.
- Status of Allowance – Provides you with the total Ceiling, total Obligations and Current Balance information for each program and fund control point (by ACC) for the fiscal year.
- FMS OBLL – Open Obligation Reports – Provides a list of obligations that are open by fiscal year. It is critical to monitor this report to ensure funds are de-obligated prior to them expiring.

RDIS (Research & Development Information System) is a component of the ePROMISe database. It consists of the RDIS Annual Report which contains information on all investigators that had approved projects in the current reporting year (Investigator Profiles), Listing of Investigators' VA approved projects (Project Funding Sheet), and a compilation of Expenditures by Investigator, Project, Administrative Agency, Cost Center, Funding Source, and Hospital Service. Previous years expenditures and summaries can be obtained from RDIS Annual Report.

What is the RDIS Annual Report?

The RDIS annual report is done following the close out of the fiscal year to report to the Research and Development Information System (RDIS) the fiscal data that occurred at the facility for research activities. Each station collects and submits the data for the RDIS Annual Report using ePROMISe. ePROMISe manages data for VA-funded, non-VA funded and non-funded research projects that are reviewed and approved by the R&DC.

One of the key components of the RDIS Annual Report is the Project Funding Sheet (PFS, previously called "Page 20") which is required for each R&DC-approved project (funded or non-funded, active during any portion of the fiscal year) by Principal or Co- Principal Investigator.

A Project Funding Sheet reports the allocations/expenditures for each project in the following ways:

- For VA funded projects, report VA Research distributions (0161A1 only) made to your station during the fiscal year.
- For projects with funds administered through and reported by the Non-Profit Corporation (NPC), report expenditures made during the fiscal year.

- For projects with funds administered through an Academic Affiliate, report allocations (Notice of Award) or expenditures made during the fiscal year.
- For projects with no funding, you will still need to complete a Project Funding Sheet listing $0.

There are several reports that can be generated including: Expenditure by PI noting the sources of funding, expenditure by Administrative Agency, expenditure by Cost Center, expenditure by funding source and expenditure by hospital service. It is due November 15 of each year, and is prepared in collaboration with the budget analyst, PIs, the NPC, the affiliate University, and the AO.

Research Services should be updating their RDIS information throughout the year to ensure accurate expenditure reporting of all funded awards, grants and contacts deemed VA research as they have gone through the VA research committees process and entered into ePROMISe before September 30th. The Research Budget Office or Budget Personnel or AO should work with the VA NPC to obtain expenditures in support of research projects administered by the VA NPC in the present VA FY. It is very important that a mechanism be created or a point of contact at the affiliate be made (generally in the Dean's Office) to assist in securing information on expenditures (or allocations) of VA research of dual appointees when funding is administered by the affiliate.

It is important to be vigilant about the accuracy of this report. You should review your projects in ePROMISe at the end of the year to make sure everything is coded correctly. Incorrect coding will affect your report and the medical center's VERA allocation.

ORD sends out guidance each year on completing the RDIS report. Trainings are also provided throughout the fiscal year by the Research & Development Computing Center (RDCC).

WinRMS

The Research Management System for Windows (WinRMS) is a SQL database using web-based computer software designed to assist VA Research Field Offices in administering VA research funds. It is available to all VA Research Field Offices at no charge; many, but not all VA research programs use WinRMS. To have WinRMS installed contact the Research& Development Computing Center (RDCC). The RDCC will send you instructions on coordinating with your local Office of Information and Technology (OI&T) and the RDCC for installation.

WinRMS interfaces with VistA to extract accounting information related to personnel salaries, purchase orders (including inter-agency personnel agreements), cost transfers, and other transactions recorded within VistA. To ensure accurate mapping between WinRMS and VistA, it is critical to use the correct fund control point (FCP) and subaccount category when placing orders and entering other financial transactions in VistA. WinRMS can be used to generate budget reports, perform budget projections, and reconcile budgets. In addition to the data automatically downloaded from VistA to WinRMS, manual entry of some data elements is required (e.g., subaccount ceilings based on ITA and TDA disbursements).

WinRMS is also an excellent resource for identifying accounting errors in research project budgets (e.g., when an employee is not paid correctly, purchase orders are erroneously charged to your cost centers/FCPs). WinRMS is incredibly cumbersome to set up, but once all the data are entered, it can be an asset for your accounting staff and can run expense reports for your investigators by project.

ORD provides monthly help desk hours to assist with WinRMS. In addition, trainings are provided throughout the fiscal year by the Research & Development Computing Center (RDCC).

RAFT – Research Analysis and Forecasting Tool

The Research Analysis Forecasting Tool, or RAFT, is a web-based software program that will help you

track all ORD allocated funds distributed to your facility. The ACOS, A/O, and/or Budget Analyst/Tech use this system to track all funds allocated throughout the year. It is also used to provide ORD with quarterly expenditure data by project.

The *Raft Budget Reports* can be viewed in several different forms. You can select a Detailed Budget Allocation or a Summary Budget Allocation. You can print quarterly allocations by Medical Center, Project, Investigator, and by ITAs. Administrative Offices can download their *Pink Sheets*, by investigator, from this system.

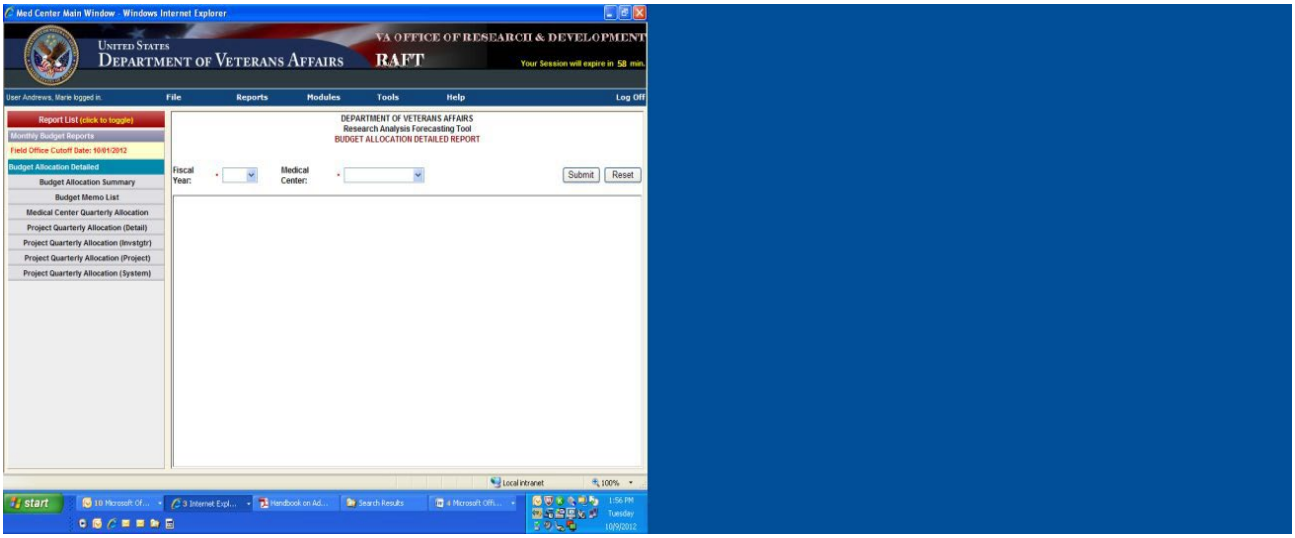
RAFT enables the capability to search for a project with criteria from words contained in the abstract in addition to Program, Account Source, Fiscal Year, and Council Meeting Date.

The *RAFT expenditure* reports are due on April 15th, July 15th, and October 15th each year. Each quarter's cumulative FY expenditures need to be reported into RAFT at the project level. Only Current Year funds are reported. Comments need to be entered into the report regarding spend plans for projects that are under executing their funds. ORD will review and may request additional information.

Trainings are provided throughout the fiscal year by the Research & Development Computing Center (RDCC).

To receive access to RAFT, please go to ORD Field Administrative Officer and Financial Management Resources (sharepoint.com) and download the RAFT access form. Follow the directions to complete and submit.

The URL for the RAFT log in is at http://raft.research.va.gov/RAFT



Additional Resources

ORD has made a concerted effort to train the field on the many factors involved in managing research funding. Please go to ORD Field Administrative Officer and Financial Management Resources (sharepoint.com) for more information on these resources.

FMS Users Guide version 5.0.1: FMS Users Guide - Financial Management System Services (va.gov) – internal to VA site.

Funding Allocation/Ceilings

What is an Initial Target Allowance (ITA)?

Every Fiscal Year, you will receive an ITA. The ITA report can be found in the Research Analysis and Forecasting Tool (RAFT) system under the Reports option and then select ITA Reports. The amount of your ITA depends on the level of VA funding allocated to the facility research program at the beginning of each fiscal year. The ITA is sent out through a Transfers of Disbursement Authority (TDAs) at the beginning of the year. It may be for the full amount of the ITA or in a Continuing Resolution year, a partial amount through the end of the Continuing Resolution.

What is a Transfer of Disbursement Authority (TDA)?
A TDA is the mechanism, or document, which sends and removes money to and from your medical center. The TDA comes in several forms including a spreadsheet from the Fiscal Service, a download from RAFT or you can request read only access to AACS Home (va.gov). Normally, TDAs have a number assigned to them. When money arrives on station, it is placed in the program as undistributed. You will then work with fiscal to move to the appropriate fund control points.

Throughout the year, you will receive TDAs adding or removing money from your facility as new projects start or funds are returned that cannot be spent. The TDAs should be tracked by the research office to ensure that the appropriate levels of funding have been received.

What is a Fund Control Point (FCP)?
A FCP is where money is allocated in IFCAP/VISTA once received at the field station. Each program should have a salary FCP and an All Other FCP assigned. The Fiscal Service has the capability to create additional FCPs, as needed. Control Points are matrixed to Accounting Classification Codes (ACC) Codes in FMS, so transactions recorded in IFCAP/VistA are also recorded in FMS when obligated.

At the beginning of each year, the ITA should be reviewed, and a plan developed on the funds that should be allocated to each FCP as the TDAs arrive on station. This will allow you during a Continuing Resolution to already have a plan in place on the FCPs (salary, All Other, etc.) that should be used as the TDAs are sent.

What is a Cost Center (CC)?
Cost centers are a way of accumulating costs among areas of responsibility. Currently the following cost centers are used in research:

Program 821

- **CC8101** – Administration
- **CC8103** – Biomedical Laboratory Merit Review
- **CC8105** – Veterinary Medical Unit
- **CC8106** – Centrally Directed Priority Areas
- **CC8108** – BLR&D Career Development
- **CC8109** – Other Designated Research
- **CC8110** – Research Career Scientist
- **CC8119** - Reimbursables

Program 822 – has CC8124 for Rehab R&D

Program 824 – has CC8134 for Health Services R&D

Program 825 – has CC8150 for Cooperative Studies Program

Program 829 – has CC8150 for Clinical Sciences R&D

Program 826 – has CC8150 for Million Veteran Program

Obligations/Expenses

It is important to understand the different types of research expenditures.

1358s and 2237s – are funding documents in VistA used to allocate funds for Research. 1358's are typically used for Intergovernmental Personnel Agreements (IPAs), patient reimbursements and Inter or Intra- agency agreements (IAA) obligations. 2237s are used for contracts and purchase card orders.

For more information about IPAs, see Section 4 – HUMAN RESOURCES

Intergovernmental Personnel Agreements or IPAs (Covered in the Human Resources Section 4). The IPA program is managed by the Federal government's Office of Personnel. The program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges, and universities, Indian (Native American) tribal governments, federally funded research and development centers, and other eligible organizations, including Non- Profit Research Corporations/ Foundations (NPCs) at each VA facility. IPAs allows for assignments to be made for people who work outside the VA to be paid with VA research funds. These agreements are normally used to acquire research expertise from a variety of sources including affiliated universities and NPCs when the required knowledge/experience is not readily available from normal VA recruitment channels, especially when seeking the help/paid collaboration from a non-citizen.

When setting up the 1358, be sure to review the IPA so that the amount and time frame is accurate for the agreement. Funds can be lost when 1358s are projected for a much higher amount and are de-obligated after the funding has expired.

Contracts – What are they and how are they funded?

Contracts are mechanisms to obligate money for services, supplies or equipment that are over the credit card purchasing threshold. Contracts are not just for large pieces of equipment and may also be used to purchase Preventative Maintenance and Inspection (PMI), Services, Equipment Leases, Animal Feed and Bedding, Animal Purchasing, Core Facility usage at the affiliate, etc. Contracts should be submitted as early as possible in the VA fiscal year. This will allow time for review and processing by RPO East or if you choose to submit locally, by your network contracting office. "Late" submission (i.e., during Q4) may not allow for adequate time to have contracts executed. Be sure to follow the deadlines (PALT Table) set by the Contracting Office that you are utilizing.

It is important to note that each facility may have different contract requirements. Be sure to work closely with the contracting office to meet your contract requirements as early as possible, as several issues need to be resolved before a contract can be in place. It is important that the prospective contractor be "vendorized" – that is, they are in the System of Awards Management (SAM) to accept federal funds. The end-user (the Research Service) must identify what services are being sought that need to be contracted (e.g., servicing of scientific equipment, animal feed, and bedding). Veterinarian services, for example, would require a Scope of Work that details the services being sought, and must provide a possible source to provide those services. Do not directly contact contractors or vendors, unless you are trying to find out if they provide the services you are seeking. The contracting process will be managed entirely by a Contracting Office. It is highly recommended that the facility identifies the needs of the contract as early as possible, as it may take several months (or longer) for a fully executed contract to be in place.

Contracts will require a 2237 upon submission of the acquisition package in FORCE. If submitting to RPO East, do not approve the 2237 until after your FORCE package has a status of "Planning (Submitted)".

(Please note that for equipment, the **2237** should indicate the PI's name and the Equipment Inventory Listing or EIL assigned to that PI, along with any relevant delivery instructions and information)

RPO EAST R&D - A dedicated contracting team, R&D Contracting Division, has been established to assist in research related procurements. Information about the team along with forms and instructions located at the R&D- Contracting Division Customer Center.

The dedicated team can assist with research-specific contracts of $50K and above in total cost (including all option years) and non-IT contracts. The RAC can also assist with Interagency Agreements (IAAs) greater than $750K. The RAC is available to assist research offices during the planning stage of the acquisition and can guide in the writing of the contract documents that are part of the Acquisition Package found in the above SharePoint site. There should be a local Contracting Officer's Representative (COR) (can be the AO or a point of contact in the Research Budget Office) to assist the Contracting Officer with more technical points regarding specific needs and requirements of the research program wanting to enter into a contract. Formal online training is required to be a COR. This training is available through Federal Acquisition Institute - Continuous Learning for FAC-COR Certification via FAI Home | FAI.GOV

Intragovernmental Reimbursable Agreements: Intragovernmental reimbursable agreements may be executed within VA between different appropriations or between VA and another Federal agency. Volume 1 Chapter 11 of VA Financial policies and Procedures (Chapter 11B - Buy/Sell Transactions (G-Invoicing) - Financial Policy Documents (va.gov)) describes in detail the utilization of these agreements. Reimbursable agreements may be entered under various legislative authorities. They are characterized as buy/sell monetary arrangements within or between Federal agencies and are a type of intragovernmental transaction. VA organizations that require support will first consider support capabilities available within their organizations, consistent with mission requirements and regulatory authorizations before seeking other sources.

Cost Transfers: Cost transfers occur when costs are incurred in a different appropriation, program, fund control point or station than where the cost should be accounted. To initiate a cost transfer, you must work with your local budget office to initiate. Normally an email is sent explaining the amount to cost transfer, where the cost was originally incurred and where the cost should be incurred. In many cases, you are transferring costs from current year to prior year or from one program to another. It is important to understand that you are transferring the cost from where it was incurred to where it should be booked. For example: from current year salary to prior year salary. If you are crossing appropriations, these types of cost transfers are more heavily scrutinized. It is best practice to have an MOU set-up describing the agreement behind the cost transfer.

Bills of Collection: Bills of Collection (BOC) normally occur when the research office should be reimbursed by the NPC or University for costs incurred. Examples include salary, animal per diems, core services etc. To initiate a bill of collection, you must have the billing menu in VISTA. The entity being billed must be vendorized in the VA system. Key points to remember specifically is to include which organization you are billing (i.e. the university or NPC). This is important because billing the NPC goes to a different appropriation than billing the university. You must know the form type, category, and appropriation. When billing the NPC, the 0161X2 FCP will be entered on the bill and when billing the affiliate, the 0161R1 FCP will be selected. Working with accounting will facilitate the generation of a bill. The reimbursements will be sent via a TDA to the site once the BOC has been processed. It is important to close the loop and complete cost transfers once the funds have arrived in the reimbursable FCP.

Payroll – Are costs associated with VA personnel. Payroll costs can be found through the Personnel and

Accounting Integrated Data (PAID) system. Reports can be generated by fiscal to help balance the books. These include PAID, gross to net, and F20.

General Post Funds

General Post Funds (GPFs) are funds donated to the local facility. In most cases, these funds have certain restrictions tied to the donation. Thus, a donor's letter must be provided by the donor of the funds to identify its use in research. Such a donor's letter can specify which PI should be allocated those funds and could specify the type of research that is to be undertaken. Your program will have standard operating procedures for how to accept and expend general post funds. Sometimes GPF expenditures are processed for approval through the R&D committee; at other facilities, the facility Director, Chief of Staff and ACOS will provide the review and approval or disapproval. Because of significant restrictions in the types of common expenses in research for which GPF funds might be used, going forward facilities are encouraged to utilize the GPF mechanism no longer for donations to individual PIs. Instead, donated funds for research should be sent to the NPC. Current GPF balances can be transferred to the NPC if there is a letter from the donor allowing the transfer.

VA Nonprofit Corporation

NPCs offer a flexible funding mechanism to manage non-VA funding in support of VA Research. NPCs continue to obtain funding from diverse sources, including private sector companies, charitable foundations, private individuals, state and local governments, universities, and Federal entities such as the National Institutes of Health (NIH), Department of Defense (DoD), and Centers for Disease Control and Prevention (CDC). Research grants administered by the NPC must be approved by the facility Research and Development Committee and are considered VA research projects. See Section 16 for more information on the NPCs.

SECTION 4 – Human Resources (HR)

Human capital is a critical element in ensuring success in research. Generally, 70 to 80 percent of the budget of a research grant or award is allocated to hire staff to perform work on the research project to generate, evaluate, and assemble the gathered research data, and to then formulate a research communication for submission to scientific meetings for presentation, and to journals for publication. The ability to recruit skilled research employees enables a research program to be productive to, hopefully, successfully compete for additional research support from various funding agencies and other sources, thus sustaining the research to be able to seek answers to scientific questions as they arise. Inability to recruit research staff inevitably leads to a non-productive research program that will not be sustainable. Given the type of funding available (VA, other non-VA sources), several mechanisms to employ research staff are available where the Research Office can assist the Principal Investigator. Anyone working in a research program at the VA *must* have a VA appointment, either paid or unpaid. Contract staff may be used to support research but cannot be part of the study team named in the IRB/R&D applications. The VA's HR policies are dictated by the Office of Personnel Management (OPM's) regulations which apply to all Federal jobs. Additional authorities have been granted to VA under Title 38. The relevant *VA Handbook* for HR staffing issues is 5005.

ORD Centralized HR services in FY 23. The purpose is to properly align hiring practices with the needs of the ORD and the research programs. Services include classification, recruitment and staffing, employee labor relations and performance management. Research programs have advisors that can be consulted with to address questions. Each site has two HR Management Liaisons that interface with Account Managers and Recruitment advisors. They can also provide you with detailed information about positions, active recruitments, Not to Exceed, awards and other matters.

Information regarding HR in VA Research can be found at Human Resources/Personnel (va.gov)

Some general principles to consider when hiring.

Appointment Types:

- VA Paid under either Title 38, Hybrid Title 38, or Title 5.
- Intergovernmental Personnel Agreement (IPA).
- Without compensation appointment authority.

Pay Plans

- General Schedule: This pay system covers the largest group of civilian white-collar Federal employees and is identified by the pay plan code GS. Salaries & Wages (opm.gov). While there is base pay applicable for the U.S., pay is different in different parts of the country based on locality even for the same grade and step.
- Federal Wage System: This pay system covers the largest group of civilian blue-collar Federal employees and is identified by the pay plan code WG.
- VM, VN and AD: These pay schedules are for employees covered under the title 38 hiring authority.

Title 38 vs Title 5

- Title 38 positions are specific Authorities provided to VA by congress allowing VA to hire Physicians, Dentists, Optometrists, Podiatrists, Chiropractors, Physician Assistants, Nurses, and Extended Function Dental Auxiliaries. Title 38 Hybrid positions include Audiologist, Psychologists Speech Pathologist, LPN, Social Worker, Nursing Assistants, etc. (Refer to VA Directive/Handbook 5005, Part III, for a full listing). There is a special

hiring authority under Title 38 that can be used to hire research staff (see below).

- The remaining VA employees are appointed under Title 5.

Tours of Duty

The usual Tour of Duty in the VA is 8 AM to 4:30 PM, but other Tours of Duty can be applied to an individual employee depending on the situation. Tours of duty can be added to the time and attendance system (the request process varies by station), and once added, can be applied to any employee whose supervisor approves that tour. All tours over six hours in duration must include a 30 min unpaid lunch break; employees also are eligible for one 15-minute break for every four hours they work. Typically, combining breaks with lunch into a one-hour lunch break is not authorized, but can be approved for employees under special circumstances.

Appointment Authorities

ORD hires mostly fall under the non-competitive Schedule B or Medical Support Authority for Research (MSA). Below is a breakdown of the different types of hiring authorities.

Competitive (Career or Term appointments)

Federal Government civilian positions are generally in the competitive civil service. To obtain a competitive service job, you must compete with other applicants in open competition. This may be done locally or nationally depending on the position. Administrative positions usually fall under competitive hiring.

- Veterans' Preference gives eligible veterans preference in appointment over other applicants.
- Temporary and term appointments are not permanent, so they do not give the employee competitive status or reinstatement eligibility. This means they don't have the special advantage that internal candidates have (i.e., they do not have status, they may not apply for permanent appointments through agency internal merit promotion procedures, which are used for filling positions from the ranks of current and former permanent Federal employees). Term appointments are limited to 4 years and cannot be renewed.

Permanent

(Title 5 U.S. Code)

- Permanent employees are generally initially hired under a career-conditional appointment (Permanent – Career-Conditional Appointment). Normally, this is the first career-type of appointment, and the appointee must complete a 1-year probationary period and a total of 3 years of continuous creditable service to attain a career appointment (Permanent – Career Appointment). (Note: If the appointee already has status as a Career employee, there is no probationary period.)
- There are limited Career/Career-Conditional positions in R&D since most of the funds are time limited. There could be Career employees in Research Administration, but these are determined generally on a position-by-position basis at the facility level.

Term

(5 CFR, part 316, subpart C)

- Term appointments (**Term 5 CFR, part 316, subpart C)** are time limited and competitive in nature and announced via USAJOBS.
- This appointment lasts between 1 to 4 years, depending on the project nature, and terminates upon completion of the project. Term appointments are only made for the expressed duration of the project.
- Term appointments are competitive in nature. Employees who have completed a four year term appointment must compete for a new position that is different from the one that they were previously assigned to. Same Position Same Agency is not allowed.
- Individuals initially appointed for >1 year are eligible for annual and sick leave, as well as health and life insurance benefits.

Noncompetitive and Excepted Appointments

Medical Support Authority
(38 USC 7405(a)(1))

- Temporary appointments for full-time staff can be made for up to 3 years at a time and can be extended indefinitely for three-year increments as long as there is sufficient grant funding to support the position. Eligible for all benefits.
- Part-time and intermittent appointments are for 1 day less than 1 year and cannot be extended. These positions are also not eligible for health insurance, FERS or TSP, but those with a part-time tour do accrue annual and sick leave. Intermittent appointments do not accrue leave.
- Positions must be grant funded and non-administrative (as defined by the applicable Qualification Standard on the OPM website). Eligible positions include, but are not limited to, Biological Science Laboratory Technician, Health Technician, Health Science Specialist, Research Pharmacologist, etc.
- You need to be able to justify to HR why this is necessary as opposed to going through the typical 5 CFR, part 302 and VA Excepted Board procedures. If you advertise in USAJOBs, then you cannot turn around and use the excepted authority to select the individual – you must follow the full 5 CFR part 302 process.

Schedule B
(Schedule B Section 213.3227(a) of the Federal Register)

Schedule B can be used for excepted appointments, meaning that you can select by name an individual with the skills that are needed for the position. This authority is only used for positions that are part-time or intermittent at the GS-11 level or above.

The individual must have “specialized scientific, technical, or professional skills” that will be applied to a research project.

- Appointments are for a maximum of 3 years. They can be renewed as many times as need to complete the research and are eligible for benefits.
- These authorities are not for administratively titled positions as defined by the Occupational Series: See Qualification Standards Section in the OPM Website.
- Hiring with an excepted appointment authority is often faster, leading people to (erroneously) call these “expedited appointments.”
- Full-time appointments must use Title 38 Medical Support Authority, reserving Schedule B for part-time and intermittent appointments.

- The number of Schedule B appointments in the VA is capped at 800. Use of Schedule B appointing authority requires approval from ORD – Request information can be found at: https://www.research.va.gov/resources/policies/human_resources/Request_ScheduleB.docx

Differences between Schedule B Vs. Title 38 Medical Support Authority

	Schedule B Authority	Title 38 Medical Support Authority
Can be used for excepted appointments	Yes	Yes
Required GS level	GS11 or greater	Any GS level
Individuals must have specialized technical, scientific, or professional skills	Yes	Yes
Can be used for administrative positions	No	No
Must be linked to a specific research project	Yes	Yes
Can be used for full-time appointments	No	Yes
For part-time or intermittent appointments	Yes, can appoint for up to 3 years with multiple renewals. Includes benefits	Yes, but can only appoint for 1 day less than 1 year, with no renewals and no benefits
Total number of appointees is capped nationwide	Yes	No
Requires approval from ORD for initial appointment	Yes	No
Required ORD approval for renewal	No	No

Schedule A Appointments
(5 CFR 213.3102(u))

These positions are to be filled by individuals with a disability, who: 1) under a temporary appointment have demonstrated their ability to perform the duties satisfactorily; or 2) have

been certified by counselors of State Vocational Rehabilitation agencies, or the Veterans Administration, as likely to succeed in the performance of duties.

Title 38 and Title 38 Hybrids
(38 USC 7401(1) and 38 USC 7405(3), respectively)

Research has limited authority to directly hire individuals covered by the Title 38 appointment authority. As previously described, this authority covers Physicians, Dentists, Optometrists, Podiatrists, Chiropractors, Physician Assistants, Nurses, and Extended Function Dental Auxiliaries. Physicians can only be hired under Research when they are being appointed for their Career Development Award. Nurses can be hired for CSP-funded studies, but a Nurse needing to be hired and paid from any other VA funding source, must first receive approval from the funding program.

Title 38 Hybrids cover occupations that provide direct patient care but are not included under the Title 38 appointing authority. This includes Social Workers, Audiologists, Psychologists, Biomedical Engineers, etc. Research has the authority to directly hire all individuals covered by this appointment authority when the employee will provide 100% support to research. These appointments are temporary when appointed under Research and will have an expiration date but may be extended as needed for as long as there is sufficient funding to support the position.

Recently, 4 additional positions impacting ORD hiring became Hybrid Title 38.

- Statisticians
- Data Scientists
- Economists
- Management Analysts (Informaticist)

Veterans' Appointments

Veterans with a 30% or more disability
(5 CFR 316 subparts C or D, 5 CFR 315.707)
Market your opportunities to veterans' organizations to leverage noncompetitive appointments leading to conversion to career or career- conditional employment of an eligible disabled veteran who has a compensable service-connected disability of 30 percent or more. Initial appointment must be a temporary appointment of more than 60 days or a term appointment. An agency may convert employee to permanent status at any time during the initial temporary or term period.

Veterans Recruitment Appointment (VRA)
(5 CFR 307)
You can hire certain veterans using noncompetitive appointments leading to conversion to career or career-conditional employment. A veteran can be converted to a career-conditional appointment in the competitive service after two years of satisfactory service.

Veterans Employment Opportunities Act of 1998 (VEOA)
(5 CFR 335.106, 5 CFR 315.611)
Your talent pool broadens when you use this authority. The VEOA is a special authority that allows eligible veterans to apply and compete for positions announced under merit promotion procedures when the agency is recruiting from outside its own workforce. For preference eligibles or veterans with 3 years continuous active-duty service.

VA Recruitment Process in Brief

There are two types of hiring processes within R&D: Non-Competitive and Competitive. Hiring for any position at the VA starts with the utilization of a classified Position Description (PD) or approved Functional Statement (FS) for the job to be filled. ORD has worked with classification to develop a range of multi-encumbered PDs that are already classified and ready for use. These are listed at Human Resources/Personnel (va.gov) and are available to Research Administrative Officers in compendium of PDS called the PD Library. If a PD is needed, HR Classifies the PD by utilizing a classification guide with a points system for the various factors in the PD, but depending on the facility, FSs may not require review by the classification unit and may only require signature by the Supervisor (and potentially the employee).
Research positions for principal investigators at the GS-11 rate or above may be classified based on the Research Grade Evaluation Guide, gsresch.pdf (opm.gov) .

The process for hiring employees moves then to Recruitment and Staffing. ORD's centralized HR utilizes a guidebook called the Required Documents Reference Manual (RDRM). This document provides guidance on submitting actions to HR. Consultations with HR are encouraged and depending on the action, may be required. The Administrative Officer can arrange these.

Request for Personnel Action

VA has implemented a program to manage positions, complete recruitment actions and initiate SF52s (request for personnel actions). HR·Smart and Manager Self Service (MSS) are web-based applications supporting HR management at each facility. There are 3 primary roles:

- ***VA Service Chief.*** The Service Chief role in HR·Smart is limited only to the chief of each Service Line/Organizational Code. The Service Chief is responsible for approving all actions for his/her direct and indirect reports before it is routed to the HR Office.

- ***VA Manager.*** The VA Manager role in HR·Smart is designed for employees' direct supervisors under the service chief to initiate actions and review their employee data. This role must be assigned to all supervisors who have at least one position reporting to him/her. **If the supervisor does not have this role the action will not flow properly.**

- ***VA Admin Officer.*** The Administrative Officer (AO) role in HR·Smart was built to support the managers in initiating actions. The current design provides access to the Personnel Office Identification (POID) level. Due to the high level of access, the AO can only see limited data and should only be given to trusted Administrative Officers. When selecting employee's, the AO should double check that they are selecting the correct employee (i.e., verify department ID). Requests for MSS access levels should be processed through the YourHR located at the Dashboard (va.gov)

Without Compensation Employees

Without Compensations (WOCs) are VA employees who do not receive any compensation from the VA. In many cases, they are employed at an affiliated University or VA non-profit corporation, or they may receive compensation from other independent funding. Note that a WOC appointment is a ***federal appointment*** requiring background checks and subject to federal regulations. A WOC appointment enables these employees to legally work at the VA facility, while complying with all R&D regulations and requirements for researchers. WOC employees are subject to VA's ethics and conflict of interest requirements. In cases of emergencies such as injury or sickness related to their work, a WOC appointment entitles them to emergency medical care at the VA. It also provides them with coverage under the Federal Tort Claim Act.

In some instances, WOC appointments may be given to individuals who are not US citizens. To review the information on which non-citizens can qualify for a WOC refer to the WOC eligibility guide https://www.research.va.gov/resources/policies/human_resources/WOC-Eligibility-Guide-for-non-US-citizens.pdf

A WOC employee ***cannot*** legally begin work at the VA prior to receiving approval from Human Resources.

Intergovernmental Agency Personnel Agreements

The Intergovernmental Personnel Act (IPA) enables assignments to be made for people who work for non-federal employers to be detailed to VA and have a portion of their salary covered from VA awards. For example, a person (not the PI) with a university appointment might be approved and funded to perform VA research, but they do not want to give up their university appointment. An IPA allows for sharing of technical expertise to VA and while it is NOT a personnel appointment, it is covered under HR policy and employees must undergo appropriate suitability and must be declared fit to perform the duties. An IPA can be setup to reimburse a full, partial or in some cases no salary. For this reason, the employee signs the IPA, meaning that the employee is willing to be assigned under the terms of the agreement; the employing or sending agency signs that it is willing to send the employee and continue to pay the employee at his/her normal salary rate, and the receiving agency signs indicating that it is willing to reimburse the sending agency at the rate set forth in the contract.

Regulatory Authorities

- The Intergovernmental Personnel Act (IPA) and its provisions are set forth in 5 CFR part 334. The act enables the "mobility assignment" of a person with specific skills, who is working for one eligible agency (such as, an institution of higher learning) to be "assigned" to work on a program or project at another agency that has a need for those skills. The act was created to facilitate benefit to both the "sending" and the "receiving" agencies, while preserving the rights and benefits for the employee on assignment. At least one of the agencies involved in the agreement must be a federal agency (e.g., VA).
- The program is managed by the Federal Government Office of Personnel Management – Intergovernment Personnel Act (opm.gov)
- VA has delineated its policy on IPA in VA Handbook 5005 Part I, Section C.

Which organizations can participate in the IPA program?

VA researchers typically use IPAs to bring individuals from an outside institution into the VA. The converse, with VA employees working at another institution, is also possible through IPAs, but is not relevant to research and is not covered here because in these situations the employee must be a permanent employee of VA.

An organization must be approved to participate in the IPA program.

- In general, academic affiliates and VA-NPCs are approved.
- VA can certify new organizations as IPA partners, but it is a somewhat lengthy process. Before embarking on this process, inquire whether this organization was previously certified with another Federal organization at any time. If so, there is no need to certify again, unless you choose to do so. To certify a new organization, submit a request to VA OHRM with the following items:
    - Cover letter describing why the organization wishes to participation in the IPA Mobility Program and how it's participation would benefit both VA and the non-profit organization requesting to participate in the program,
    - Articles of Incorporation,
    - Bylaws,
    - Internal Revenue Non-profit Statement, and

- Any additional information describing organization's functions related to public management concerns of governments or universities:
- Includes professional advisory services, research, educational or developmental services, or any other services to governments or universities concerned with public management.

Which individuals can come to the VA on an IPA?

- The assigned candidate must have worked for the "sending" agency for at ***least 90*** days in a position that is considered ***not temporary***.
  - This becomes a challenge for employees of VA-NPCs since the VA cannot reimburse the VA-NPC for the first 90 days.
  - This requirement is not satisfied by hiring the individual at the VA-NPC on an unpaid basis for 90 days.
- IPAs are not to be used to acquire administrative, clinical staff, or patient care services.
- Students, including graduate students, are not eligible for mobility assignment under an IPA.

Term Limits of IPAs

IPAs are meant to be temporary as a process for exchanging skills between organizations. In practice, it benefits VA research to access the skills of individuals on IPAs for extended periods of time. As a result of the Cleland Dole Act, IPA time restrictions were removed, thus an IPA can now be extended in 2-year increments as long as project funding is available. This only applies to research IPAs.

- The initial IPA should be set up for 2 years.
- Subsequent IPAs can be renewed/extended for two-years at a time.
- While Federal employees may not serve more than 6 years on an IPA assignment during their career, this limitation does not apply to private sector employees working on VA Approved Research projects.

Setting Up an IPA

1) Verify that the 'sending' institution is eligible to participate in the IPA program (see above). Verify that the individual in question is eligible to participate in the IPA program, e.g., that they have worked for the "sending" agency for at least 90 days in a position that is considered non-temporary.
   - This can be done by requesting a very simple letter on the university or NPC letter head, or email signed by someone in authority (same person signing the OF-69, signatory official, head of sponsored programs, their chief HR, etc.) that simply states, "Mr./Ms. is an employee of the name institution hired on X date on a non-temporary appointment".
   - Complete an OF-69.
   - There is a detailed PowerPoint on the method for completing IPA paperwork at https://www.research.va.gov/programs/nppo/docs/Intergovernmental-Personnel-Act.pptx
   - IPAs are authorized and approved by the following individuals:
     i. Director, CFO, manager, current employer
     ii. Director, local VA Medical Center requiring the services.
2) Funding for IPAs is through 1358s under exception 20.
3) VA policy does not allow the payment of administrative costs on IPAs (see Handbook 5005, Part I, Chapter 3, Section 2 (l))
   - *"l. Indirect administrative costs associated with preparing and maintaining payroll records, developing reports, negotiating the IPA agreement, office space, furnishings, supplies, staff support, and computer time are prohibited."*

Those on an IPA Have Federal Tort Coverage and Do Not Require a WOC Appointment

The two types of IPA assignments are appointment and detail. Under five U.S.C. § 3374(b) appointees have FTCA coverage and under § 3374(c) detailees have FTCA coverage. The statute is slightly confusing because § 3374 only refers to those assigned from a "State or local government." § 3374, through § 3372, also applies to those assigned to VA from universities and NPCs. Section 3372(e)(2) (general provisions of the IPA subpart), states:

"…an assignment of an employee of another organization or an institution of higher education to a Federal agency, and an employee so assigned, shall be treated in the same way as an assignment of an employee of a State or local government to a Federal agency, and an employee so assigned, is treated under the provisions of this subchapter governing an assignment of an employee of a State or local government to a Federal agency."

In other words, whether from a "State or local government," an "other organization," or "an institution of higher learning," an IPA assignee to VA is subject to the provisions of § 3374, which means that all IPA assignees from these entities have FTCA coverage. Because universities fall within the definition of "an institution of higher learning" (see § 3372(b)(2) and 5 C.F.R. § 334.102), and NPCs fall within the definition of "other organization" (see § 3371(4)(C)), all research assignees to VA are subject to the provisions of § 3374, which means that they are all covered by the FTCA.

Joint Personnel Agreements (JPA)

Though similar to an IPA, a JPA is a contract between a VA Non-Profit corporation and a university affiliate. At a VA where a formal Research Affiliations Agreement exists that includes the local VA non-profit as a signatory in addition to the VA itself and the academic affiliate, JPAs can be executed to include scientific and technical personnel but not administrative personnel. Joint Personnel Agreements are executed on a year-to-year basis, but without time limitation, provided funding is available for the position.

Factors to Consider When Hiring VA Employees in Research Service

- Determine the period of funding for which the position(s) will be encumbered.
- Determine if the budget for the project allows for full or part-time employees.
- Know the source of funding (where the funding for hire will be administered) for the prospective employee – is the funding from VA appropriation, Affiliate (University), or VA Non-Profit Corporation?
- Consider the background of the candidates when looking to hire employees – do the prospective candidates have qualifications that meet the type of job that they will be performing?
- Consider the grade level needed to perform the work of the project.
- When recruiting or appointing a candidate with superior qualifications and/or to meet a special need of the agency for the candidate's service, with appropriate approvals, you may be able to set the rate of basic pay above the minimum rate of the appropriate General Schedule (GS) grade.
- Clinical personnel need to be credentialed, meaning that they undergo a systematic process of screening and evaluation of their qualifications and other credentials, including licensure, required education, relevant training and experience, and current competence and health status.
    - Credentialing is different from Privileging, which is the process by which licensed independent practitioners are allowed to provide specified medical, or other patient care services at a specific institution. In the VA, privileging is accomplished through the VetPro online system (see Section 8).

Disciplinary Actions and Union Interaction

There is no requirement for Union officials to be present for the performance review of union member

staff. However, if any disciplinary actions are being contemplated for an employee covered by the union, you should contact your HR department and coordinate your efforts with them.

Union representatives should know who you are if you have union members on your staff. Developing a collegial relationship is a good idea. Remember, your staff have the right to have a union representative with them in disciplinary proceedings.

If an employee is not performing as required, then the employee's supervisor needs to address the problem. Usually, issues are minor and can be handled in an informal one on one meeting. Remember to document everything and keep good notes, you should also follow up with the employee with a written summary of the meeting. Sometimes issues are more problematic, and a plan needs to be developed to address it. Work with your HR department to follow the accepted process to do this. Your HR department will also guide you through the process if the employee needs to be separated from the VA.

On-the-Job Injury

If you have an employee who is injured or made ill "on the job", then – first and foremost – you must ensure that the employee receives the help they need, *as soon as possible*. They may be sent to your local employee health clinic or to the Medical Center Emergency Room. The event should be documented by the employee, as well as by anyone else involved or witnessing the event using a Report of Contact form. The employee is responsible for initiating an incident report in ECOMP. Link to ECOMP: https://www.ecomp.dol.gov/. Employees will be required to register and submit their own injury report (OSHA Form 301) and if they choose, they can then complete a CA-1 or CA-2 injury claim.

Performance Appraisals

The VA uses a Position Description-based performance appraisal system. You are required to meet with the Title 5 and Title 38 hybrid employees you supervise three times a year. The first meeting is to initiate the appraisal for the current rating cycle, which is done in October or within 30-days of hire. The initiation documents that employees have a copy of their performance plan and understand their duties, which is recorded through signature on the form. The second meeting is to document the mid-year progress review and typically occurs in April/May of each year or mid-way between a new hires onboarding date and close-out. This meeting can also be used to determine if any changes need to be made to the performance plan. The third meeting is for close-out and occurs in October. This meeting provides the employee with their final rating for the year and can also be used to initiate the next year's performance plan.

All VA facilities are now required to utilize the electronic system called ePERFORMANCE. The system is used to electronically sign and document meetings on the performance appraisal form. The system also allows the supervisor and employee to upload documents and notes to be used during the final rating throughout the rating cycle.

Management Tip I: Do not wait for these meetings to address performance successes or opportunities for performance improvement. Make it your goal that if a meeting is required, that none of the required meetings referenced above contains anything that will surprise the staff you supervise.

Management Tip II: When documenting an employee's shortcoming, be as specific as possible. A Performance Improvement Plan (PIP) can be instituted with milestones that the employee must meet to demonstrate improvement in work performance. It is always better to attend to employee performance early rather than later and especially if one needs to do so during the employment probationary period just after hiring. Letting problems linger will generally make them worse and may lead to unwanted escalated actions. Above all, **be consistent** in your dealings with your employees.

Management Tip III: Performance awards for VA-paid employees on the Research appropriation will come out of the VA Award (e.g., Merit Review) that employee is assigned to. Close monitoring of the performance awards needs to occur otherwise funds to complete the proposed scientific work may be short. Some facilities provide performance awards for employees who receive a Fully Successful rating or better, others only provide performance awards for Excellent or higher. You will want to check with your local leadership to determine which rating is eligible for a performance award and the amounts for those awards. This will allow you to stay consistent with your local facility when submitting awards for research employees to centralized HR.

Incentive Awards

Some Research Services have the authority to process Incentive Awards, others may fall under the Awards Program of the medical center. For awards tied to research employees under HRMACs, awards are submitted to the Field Ops representative assigned for review and approval. For staff under local jurisdictions, the HR department at the facility/VISN will have a person designated as a coordinator for Incentive Awards and can be very helpful regarding how to process these. The form used is VA Form 4659 – *Incentive Awards Recommendation and Approval*.

These awards are broken into following categories:

- Special Contribution: An accomplishment achieved through an individual/group effort in the form of a special act or service in the public interest connected with or related to official government, which contributes to the efficacy, economy, or other improvement of Government operations, or achieves a significant reduction in paperwork, or a contribution or accomplishment in the public interest which is a nonrecurring contribution either within or outside of the job responsibilities.
    - It can be given as many times as earned.
- Time Off: An award granted as an incentive to reinforce acts by an individual/group of employees deserving recognition. It is granted as time off from work that is not charged to any type of leave or official duty time or authorized absence.
    - Increments of 1 hour
    - Minimum: 4 hours
    - Maximum: 40 hours/80 hours in a year
    - Must be used within 180 days of approval.

Quality Step Increase (QSI)

A QSI is an increase to an employee's rate of basic pay from one step of the grade to the next step that is granted in recognition of excellence in performance during the last appraisal cycle. The purpose of such increases is to recognize consistently high achievers by granting faster than normal step increases. Only General Schedule (GS) employees are eligible to receive QSIs.

A QSI not only increases an employee's base pay, but also increases the amount of retirement benefits; the amount of Government Life Insurance for covered employees, and often results in a higher basic pay adjustment upon promotion of the employee.

A QSI cannot be granted to an eligible employee who has received a QSI within the preceding 52 consecutive calendar weeks, or who is at step 10 of the pay grade. It can only be given at the end of the rating period and is considered the performance award for that period.

Managing Office Schedules and Leave

As AO and ACOS, you need to understand and execute the best schedule for your administrative and

VMU staff.

You must establish procedures for staff to report in sick and request leave. You do not manage the schedule for researchers reporting to a PI. You may be the administrative supervisor of research staff for HR issues, but all scheduling and scientific oversight is the responsibility of the PI or lab manager. The ACOS is the supervisor of clinical and non-clinician Principal Investigators in Research Service, be they VA-paid or a WOC Principal Investigator.

The ACOS may also be the approver of Overtime and Compensatory time and may also be responsible for approving Exceptions – these are items such as an employee not putting in the correct leave in a timely fashion, putting in a late timesheet, etc.

Things to consider before approving leave include cross-coverage, inspection schedule, and overall office staffing.

Sometimes staff work "too much" and need to be encouraged to take leave. Others take leave frequently and have low balances. As AO, consider mentoring staff regarding the best form of work/life balance.

If you have questions about schedules or leave, your HR (or Payroll) department should be able to answer them.

Liaison with HR

As AO, you are an important liaison between the Research service and HR. It is important to develop good working relationships with the HR Account Managers and Recruitment advisors.

Sabbaticals - Local

VA Funded PIs planning to enter into sabbaticals during active project periods are required to submit a request for a project modification (see: ProjectModification) no less than 6 calendar months **prior to** initiation of the sabbatical for approval to participate in the sabbatical during the project period. The request should include a plan for continuing the research while on sabbatical, temporarily suspending the research, or transferring the research to another PI for an interim period of time. Failure to notify ORD about a pending sabbatical may result in termination of funding for the project.

SECTION 5 – Applying for VA-funding

eRA and Merit Review

Funding for research can come from a variety of sources: Federal, State/Local Government, Private Industry or Non-Profit organizations. Federal sources of funding can be intramural VA funding (primarily through VHA Office of Research and Development (ORD) programs (see below), occasionally through specialty initiatives with medical care dollars for projects that meet the criteria of research, or extramural funding from sources such as the National Institutes of Health (NIH), Centers of Disease Control (CDC), and Department of Defense (DOD). Extramural funding will be administered by either the VA Non-Profit Corporation or the affiliated university (Sections 15 and 16).

In 1952, the VA decided that providing funding for research was one of its important goals (see history). VA intramural funding for research is processed through ORD and is organized into a number of programs and managed portfolios that reflect VA research strategic priorities. Eligible researchers within the VA (see PI Eligibility below and *VHA Handbook* 1200.15) can apply for VA ORD funding for protocols that fall within funding opportunities listed as Requests for Applications (RFAs) and Solicitations on the VA ORD intranet website (see: Requests for Applications (RFA) and Program Announcements (va.gov).

- Merit Reviews are funding given to an individual (or co-PIs), and typically last 3 to 4 years. These awards are similar to NIH R01 grants. The Merit Review program is an intramural, peer-reviewed funding mechanism to support investigator-initiated research of disorders and diseases of importance to the health of Veterans. Go to the ORD Funding page for more information
- Career Development awards provide salary for early career investigators. These are similar to NIH K01 and K08 awards (see more about the Career Development Program in the section on Growing a Program).
- Research Career Scientist (RCS) awards provide salary for outstanding non-clinician senior investigators with a strong track record of VA research accomplishments and service and are like NIH K05 awards.
- COIN and Center awards support a group of researchers in HSRD or RR&D who are working around a common topic. In some rounds, only existing Centers can apply for renewal depending on availability of funds. These are like NIH Program Project or Center awards.
- Pilot Award RFAs are periodically offered in select topic areas, and the RR&D Program uses the SPiRE (Small Projects in Rehabilitation Research) Award mechanism.
- In addition to these ORD-funded programs, the VA ORD intranet website also lists current QuERI Program RFAs (listed under HSR section). QuERI (Quality Enhancement Research Initiative) programs are funded by medical care dollars, not ORD funds, and funding is therefore issued as single year appropriated dollars, not 2-year appropriated dollars (like ORD funds).
- Because VA is an intramural program, these funds are called “awards” not “grants.”

Funding Programs - ISRM

The VA research programs are organized into the following groups (Note that this will be changing starting FY 25 as ORD transitions to the portfolio structure as noted below. ***Because this program continues to evolve, it is highly suggested to get the most recent information at Investigators, Scientific Review and Management (ISRM) (va.gov)***)

Historically the programs were broken into the following services.

- **BLR&D (Biomedical Laboratory Research and Development) – Program 821** – conducts research that explores basic biological or physiological principles in humans or animals but does not involve intact human beings. For example, it includes research on animal models and investigations of tissues, blood, or other biologic specimens from humans.
- **CSR&D (Clinical Science Research and Development) – Program 829** – conducts research that focuses on intact human beings as the unit of examination. Examples include interventional and effectiveness studies, clinical, epidemiological, and technological studies.
- **The VA Cooperative Studies Program (CSP) – Program 825** is the Division of VA Research and Development that is responsible for the planning and conduct of large multicenter clinical trials in the Department of Veterans Affairs. Applications to the CSP program follow a separate set of procedures from VA Merit/CDA/Pilot funding RFAs (VHA Handbooks 1205/1205.01).
- **RR&D (Rehabilitation Research and Development) – Program 822** – conducts research to discover knowledge and create innovations that restore Veterans who have become disabled due to injury or disease to their greatest possible functional capacity in their families, communities, and workplaces.
- **HSR&D (Health Services Research and Development) – Program 824** – supports research to improve the delivery of healthcare to Veterans. Among the areas studied are quality and organization of care; patient access and outcomes; and cost-effectiveness. The division's Quality Enhancement Research Initiative (QuERI) is designed to translate research findings into advancements in Veterans' care.
- **Million Veteran Program (MVP) – Program 826** – supports large genomic/genetic and related data science research using the MVP cohort and enterprise resources. This division works with the ORD services and/or CSP on applications and RFAs that involve MVP resources (including biospecimens and data). The process for applications works through MVP and may use the service RFA mechanism (e.g., through BLRD or CSRD) as appropriate.

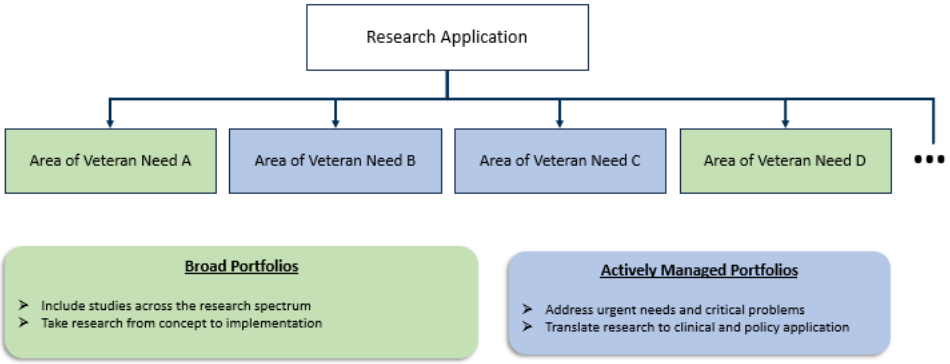
Starting in FY 25, ORD underwent a reorganization in the way scientific review services were structured. This included a major transformation regarding the submission and review processes. The intent is to implement new processes that enable investigators to navigate the VA Research application process more efficiently and rapidly launch research that improves the health and healthcare of veterans. In addition, uniform eligibility requirements and uniform budget caps will be implemented.

The main changes include:

- **Programmatic Realignment into Portfolios**: The current services are replaced by portfolios of Veteran need, and descriptions of current portfolio offerings will be maintained on the ISRM web page (***Investigators, Scientific Review and Management (ISRM) (va.gov)***). The current portfolios consist of Actively Managed Portfolios and Broad Portfolios:
    - Actively Managed Portfolios (AMPs) will provide funding to address specific areas of Veteran need. The type and number of AMPs will vary over time to ensure focus on critical

and emergent areas of Veteran need, but currently the inaugural AMPs were Traumatic Brain Injury, Suicide Prevention, Pain/Opioid Use Disorders, Military Exposures, and Precision Oncology.

- Broad Portfolios will continue to provide funding for a wide range of investigator-initiated research from discovery to translation and also support the Career Development, Research Career Scientist, Centers, and Service Award programs. There are currently 4 Broad Portfolios for Medical Health Research (MedHealth), Brain Behavior and Mental Health Research (BBMH), Health Systems Research (HSR), and Rehabilitation Research, Development and Translation (RDT).



- **Distribution of Funding to Stations Consolidated into Fewer Program Fund Codes:** Funding from all portfolios will now be issued to stations primarily as Program 821, with CSP Studies continuing to use Program 825. Other programs (822, 824, 826, 829) will remain until all awards issued under those legacy programs have ended, and thereafter be retired.
- **Streamlined/Consolidated Requests for Application, Introduction of Notices of Special Interest:**

  - Requests for Applications (RFAs) were standardized for use across all of the portfolios, to reduce confusion over submission requirements for given types of funding applications. Historically, there were dozens of RFAs posted, unique to each service, and currently there are only 7 harmonized for use across all portfolios (Requests for Applications (RFA) and Program Announcements (va.gov)).
  - Portfolios publish, and periodically update, Notices of Special Intent (NOSIs) which describe the purview of the portfolio, for which RFAs they are currently accepting applications, and the areas of research that they are particularly interested in funding at present.
  - All submissions now require a pre-application (in the past, Intent-to-Submit forms were completed online for HSR&D, and RR&D/some CSR&D Merits along with all CDA applications required Letters of Intent).

The process for applying for and receiving VA funds for research is described at this webpage: Funding (va.gov). A listing of the current RFAs and NOSIs can be found at Requests for Applications (RFA) and Program Announcements (internal to VA). For each application type RFA, there is an accompanying pre-application RFA, with specific instructions and requirements for completing a pre-application submission unique to that particular application type (e.g. CDA, Pilot, Merit). Note that deadlines for pre-application submission may vary, with CDA Awards and Clinical Trial Merits for example having earlier deadlines than other types of applications; be sure to review the deadlines specific to your RFA and pre-application RFA well in advance.

Each RFA will describe details of investigator eligibility, budget caps and restrictions (if any), and provide a very detailed breakdown of exactly what components must be submitted for a valid application to be accepted for review. As these elements may vary across RFAs, it is always critical to read the RFA

specific to the intended application type completely and follow the instructions precisely. In addition, the NOSIs for the portfolio to which the application is intended to respond must be reviewed to ensure that they are accepting the applications from the RFA of interest at this time (e.g. Merit vs. CDA-1 vs. CDA-2 vs. Pilot). Also, the NOSIs will identify whether there are any unique investigator eligibility considerations specific to the given portfolio (e.g. the Medical Health and the Brain, Behavior and Mental Health Portfolios currently limit the number of NEW non-clinician applicants from each station in any given round of review).

In addition to the RFAs and NOSIs which provide detailed current requirements for application, certain VHA Handbooks and Program Guides may also provide more general policy, criteria, and guidance on select topics such as CDAs, Offsite Waivers, the Research Career Scientist (RCS) Program, Research Centers, and Centralized Position Management/Promotion for non-clinician investigators. However, these Handbooks are not updated as regularly as the RFAs and NOSIs, so the most current requirements should always be verified in the RFA posted for a given application cycle, and questions referred to the particular portfolio point of contact listed in the NOSI.

Eligibility to Submit for VA Research Funding

There are certain requirements that must be met, including:

- All applicants must meet criteria for employment as a VA employee, including United States citizenship.
- Licensed clinicians must have a VA-paid clinical appointment of at least "5/8ths" time to receive funding. Please contact the Chief of Staff at the local VA Medical Center to learn about clinical opportunities. ORD defines a clinician as a licensed practitioner with a doctoral degree (MD, DO, DDS, or clinical PhD, etc.) who treats patients at a VA Medical Center (VAMC). The VA Medical Center is expected to provide protected time to the clinician, with appropriate back-fill of clinical effort released to provide the research time, using VERA funds generated by the intramural award (see below on Protected Time for Clinician Investigators and Relationship to VERA).
- Recipients of VA funding must already have or be able to accept at time of award a minimum of 5/8ths VA-paid appointment.

In certain cases, ORD may agree to confer eligibility for individuals with less than 5/8ths appointment. The local VAMC Research Office can request such a waiver.

- For example, recipients of NIH K awards are required to spend 75% of their time at the applicant institution (the affiliate). Individuals with significant effort committed to other grants, such as NIH RO1s may not have the 25 hours per week to devote to the VA for a 5/8ths appointment.
- Time commitment to administrative or clinical activities at the affiliate is not usually accepted as a reason to issue a less than 5/8ths waiver.
- Waiver requests are program-specific, require detailed justification, and must be approved prior to Merit application submission. Waivers are made on a case-by-case basis as requested by the facility Director and endorsed by the ACOS for R&D and the facility Chief of Staff. Conditions of approval (e.g. waiver duration) will vary according to circumstances (e.g. after a K-award ends, an investigator may be required to take up at least a 5/8ths VA-paid appointment to maintain eligibility).

Submission Process

The submission process for most VA funded research is done electronically. The process begins with ensuring that an Investigator has a Commons ID (CID) in eRA Commons with an affiliation to your medical center. Instructions can be found here.

The researcher identifies the RFA for which they wish to apply. The VA SF-424 APPLICATION GUIDE is the guide that helps the investigator to complete the elements of a successful application. The SF-424 will give way to the NIH's Application Submission System and Interface for Submission Tracking (ASSIST) where the Investigator submits his/her proposal directly and the Research Office only signs off on the submission.

General information about VA funding can be found on the Internet. However, VA's specific RFA's can only be found on the Intranet and can only be accessed with VA computers.

Once the investigator has completed the application, it must be submitted through an authorized agent in the research office. This is usually the AO, or someone delegated by the AO. Sometimes it is the ACOS. At many facilities, there is a mechanism in place to pre-review the submission before it is uploaded. At others, it is entirely up to the investigator to ensure that the application is complete and correct. The eRA Commons system will scan the document for basic elements and will return a notification of either errors or warnings. Errors indicate a "fatal flaw", which will not let the application proceed to submission and must be addressed. Warnings will not prevent the application from being submitted and may or may not need to be addressed. However, there are other "fatal flaws" that are not detected by this system, such as budget caps, font size, margin size, and writing style. There are 2 days from the time of upload to submission to pull the application back and correct any issues. This is the last window of opportunity to make any changes to the submission. *The 2-day window is only available if you submit 2 days prior to the application submission deadline. Any changed/corrected applications submitted after the submission deadline will be withdrawn*.

System for Award Management (SAM)

The System for Award Management (SAM), as mentioned in Section 3 – Finance, must be active at the Medical Center for any VA award to be submitted through the *Grants.gov* system. It is important to monitor your facilities expiration date to ensure your SAM registration date does not expire. To renew your SAM.gov registration, contact Ellen.Swinton@va.gov or the EASS helpdesk va.acquisition.systems@va.gov.

To determine your site's expiration data, you can go to SAM, log in using your login.gov credentials. You may need to set up the account when first logging in. After logging in, go to the search tab (SAM.gov | Search) and enter the UEI number for your VAMC. If you need more details just click on the institution name – you'll get the full address (including ZIP+4) and congressional district, everything you need for the performance site section of your grant applications!

Pre-Review

It is a good idea to designate an administrative research staff member to pre-review all Merit proposals before they are submitted to ORD. Even though the upload system uses the NIH eRA Commons system, which checks the submission for completeness, this system will not detect all errors (such as, wrong font size, wrong margin size, and budget mistakes). Also, this system does not check the content for tone or details addressing important elements of the RFA. Often the AO or a Grants Manager is the best person to pre-review submissions so that it will not be rejected for an administrative or formatting error.

Another common problem with Merit proposals is because it uses the NIH's submission system, researchers may think that their proposal should be just like their NIH submission. It is very important to

ensure that Investigators carefully follow the RFA and VA SF-424 APPLICATION GUIDE, as they differ from NIH RFPs.

Award

All submissions are reviewed by a panel of peers and experts in each area of research. Each submission is given a score from 100-500 – The lower the score, the better. A decision is made in central office as to what score level the funding will cover. So, in one year, a score of 160 might be funded, but in another year, funding might only extend to scores of 120 or lower.

Once it is determined that a submission will be funded, then all the approval documentation must be submitted. This is called the Just-in-Time (JIT) process and is completed through eRA Commons. The research office or PI will upload the various local forms and approvals needed. However, only the Signing Official can submit the forms for review. The Program Officer will review the documents and either approve or require additional clarifications/changes. Funds are released to each station and the AO and/or Budget Analyst are notified of the receipt of funds. The research can begin when ORD has approved all JIT requirements, and a start date has been awarded. Funds supporting the research proposal can be spent after central office sends it to the station.

Post Award

PI's are required to submit an annual Research Performance Progress Report (RPPR) and Final RPPR. This is done in eRA Commons using the NIH eRA Commons RPPR Module. The annual report is due 45 days before the next budget period's start date. Notifications are sent to the PI 60 days prior to due date, 30 days prior to due date and approximately 4 days after the due date.

The Final RPPR is due within 120 calendar days of the project performance end date. The PI and Signing Official will receive notifications 10 days after performance end date, 120 days after performance end date and 30 days after due date.

Both the annual RPPR and Final RPPR are prepared by the PI and routed to the Research Office's Signing Official for submission. More information on the process can be found at Federal-wide Research Performance Progress Report (RPPR) and Final RPPR for VA Investigators.

OTHER AWARDS:

ShEEP (Shared Equipment Evaluation Program) and LAMb (Laboratory Animal Major Equipment) Program

The purpose of the ORD Shared Equipment Program is to fund the purchase of major common resource shared equipment, or core animal facility major equipment to be used in VAMCs to support biomedical research on behalf of investigators associated with all ORD services.

- The ShEEP program requires in-kind partnering, or direct contribution from other sources.
- Factors considered in evaluating the requests include evidence that the equipment will be used by multiple funded VA investigators.
- The dollar amounts available to fund these requests vary by year and additional funds often become available late in the fiscal year. These equipment purchases involve contracts that may take a lengthy time to process because of the dollar amounts involved ($75,000 to $600,000). It is suggested that the research program identify their needs, complete as much of the paperwork as possible, and have the request ready to go in anticipation of a funding announcement.

Go to ISRM Notices of Special Interest (NOSIs) and Requests for Applications (RFAs) (va.gov) and search for ShEEP to see if a current RFA is available for submission. Current information is also provided at Laboratory Animal Major Equipment (LAMb) Program and Shared Equipment Evaluation Program (ShEEP).

Research Career Scientist

The Research Career Scientist Award (RCS) is intended to provide dedicated salary support of 5/8ths - 8/8ths for non-clinician scientists who have an established, independent research program at the VA for at least 3 years and have been funded by VA awards or other national peer-reviewed research support as a Principal Investigator for at least 6 years. In addition to this demonstrated track record of VA and extramural funding, the highly competitive RCS application requires demonstration of significant collaborations with other VA investigators, mentoring of junior VA investigators including ideally CDA awardees, an excellent publication track record, and evidence of substantive service both to the local Research program and nationally to VA research (e.g. serving on peer review panels). Successful awardees receive 5 years of salary support outside of a VA Merit Review Award at the RCS entry level. A satisfactory mid-stage progress report (2.5 years post-award) is required, and renewal beyond the 5 years of support requires a competitive RCS renewal application. For those Career Scientists who have demonstrated to be highly productive leaders and achieved both national and international stature and have had continuous VA funding for a minimum of 6 years, application can be made for the Senior RCS award, which provides 7 years of salary support between competitive renewal applications (with mid-stage progress report at 3.5 years).

SECTION 6 – Travel

Traveling on VA Time

One of the more confusing and more challenging events that a researcher may experience, is traveling on "company" time. There are multiple variables to be considered when a VA employee travels, including the purpose of the travel; whether they are on VA duty time, or annual leave; whether the travel is domestic or international; and the source of the funding for the travel.

Are they traveling on "official VA business"?
Examples:

- Attending a VA training conference
- Participating in an ORD-sponsored meeting such as a peer review panel
- Giving an official talk about VA policy using slides that have been vetted by VA administration.
    - Another interpretation is that it is travel that is required as part of your VA job.
    - Discussing your research at a meeting is not necessarily officially representing the VA, even if the research is VA-funded (see below). If traveling on official VA business, the traveler should be on VA time and VA is responsible for the travel expenses. Note that a traveler might choose to pay for part of the trip with non-VA funds (so-called "donated" travel, see below), but the VA is technically "on the hook" to pay for any travel that is required as part of a person's VA job.

Do researchers need to be on "official VA duty time" to discuss their research?

- Talking about your research is <u>not</u> representing the VA in an official capacity. After all, the publications have a disclaimer that says "This does not represent the views of the Department of Veterans Affairs"
- You cannot talk about VA <u>sensitive</u> information (i.e., Veteran identifiers), which you wouldn't be doing anyway.
- To talk about your VA research while not on VA time, you only need the approval of your supervisor. That can be done as a blanket memo from the supervisor allowing you to discuss your VA research at any time.

Are VA funds being used to pay for the travel?

- VA funding for travel might come from ORD. This is called "cross-funded" travel or "alternate station funding."
- Another VA station may sponsor the travel (e.g., a VA Center sponsoring a meeting requiring VA employees from other stations to attend) and this is also deemed "alternate station funding" or "cross-funded" travel.
    - Example: Participating in an ORD function such scientific panel.
- VA funding might come from the individual's VA-funded award.
    - Example: Attending a scientific meeting when that travel was included in the budget of their Merit Review award.
    - Example: Traveling to collect data at a remote site when that travel was explicitly included in the proposal and in the budget for the Merit Review.
- VA funding might come from the local VAMC's travel budget.
- In general, if VA funds are used to pay for the travel, the traveler should be on VA duty status or VA time.
- If part or all of the travel cost will be funded by another source, then this is referred to as "donated" travel (see below for additional information on processing donated

travel, including the need for OGC Ethics review of the donation for possible financial conflict of interest).

Are funds being donated by another entity to pay for the travel on VA time?

-
- Donated funds to cover travel are considered "gifts" to the VA.
- Form 0893 is submitted to Regional Counsel describing donated funds, along with Appendices A through D, which provide detailed information about the travel plans, funding sources, and expenditures.
- If funds for a trip are being donated, the traveler MUST request "Official Travel" and be on VA duty status and time, authorized absence (see below) is NOT appropriate.
- VA Form 0893 is used to accept a gift of travel under 31 U.S.C. §1353 or 5 U.S.C. §4111 and does NOT replace travel authorization documents.

Are they traveling on VA time?

If the purpose of the trip is part of the activities for which the individual was hired by the VA, then they may travel on VA duty status or VA time. They are not required to take annual leave.

- Example: An investigator presenting their VA research findings at a scientific meeting. Dissemination of research findings and exchange of information at scientific meetings is an important component of research. If the research being discussed is VA research (VA-funded, or not-VA funded but approved by the local R&D committee as VA research), then travel could be conducted on VA time.
- It is recognized that over the span of their career, an investigator conducts a body of research and not all of that can be uniquely parsed into VA versus non-VA research.

When is Authorized Absence Appropriate?

Because authorized absence is NOT an official VA duty status, it should not be used when the employee is traveling on VA duty status or using VA funds to pay for the travel. However, granting authorized absence to an employee without charge to leave may be appropriate when:

- The activity is considered of substantial benefit to VA in accomplishing its general mission or one of its specific functions, or
- The activity will clearly enhance an employee's ability to perform the duties of the position presently occupied or may be expected to prospectively occupy, or
- The basis for excusing the employee is reasonably consistent with prevailing practices of other Federal establishments in the area concerning the same or similar activities.
- The amount of authorized absence that a person can take each year is limited. OPM is currently considering limiting it to 10 days per year.

Is the travel international or domestic?

Approvals for international travel while on VA duty status are relatively complex and require a substantial amount of lead time for processing (e.g., >3 months). Some travelers choose to forego this process and instead take annual leave. However, that is not an option if the traveler is using VA funds or must be on official VA duty status because they are representing the VA on official VA business.

International travel on VA duty time requires the use of an "Official Passport", which has a burgundy-colored cover. The VA passport office must receive the request 60 days in advance. An official VA passport can be obtained through the VA International Travel Office (officialpassports@va.gov). Follow the process described below to initiate the request for foreign travel passport and authority. While

applying for your burgundy Official passport, you must temporarily surrender your blue passport. Thus, for several weeks, you will have no passport at all.

You can have a combination of VA time and non-VA time on a given trip. While on VA time for foreign travel, you use the burgundy passport and while on personal time you use the blue passport. You must enter and leave the country on the same passport (red-red or blue-blue). The number of days on AL must be fewer than the days on official travel.

Processing a VA Foreign Travel Request

To begin the foreign travel process you must first access the **Foreign Travel Portal** and follow the steps. You will be prompted to complete the VA Form 0900 Country Clearance, save (location of your choosing) and then upload in the Foreign Travel Portal. Once submitted the international travel office will review your VA Form 0900 and provide applicable instructions to obtain a government passport and/or visa based on your foreign travel request. **This travel requires Under Secretary approval. Please follow instructions and submit all documentation as soon as possible to prevent any unforeseen issues.**

For additional information regarding foreign travel requirements, please see **VA Financial Policy, International Travel**.

If you have additional questions regarding international travel, please contact them at InternationalTravelService@va.gov.

Your package must be uploaded and submitted in the SharePoint no later than **60 days prior to your departure.**

- Authorized absence (AA) is not a type of leave status. If funds for this trip are being donated, **YOU MUST request "Official Travel"** NOT AA.
- In addition, if annual leave (AL) is being taken in conjunction with this request, AL **CANNOT** exceed the number of official travel days being requested.
- Time Zone Adjustments can only be requested **IF** the total travel duration is **OVER 14 hours** to include layovers and the fare must be coach class.
- **ALL** funding sources must be included in the estimated cost of the trip (personal funds are a type of funding source and if AL is being taken in conjunction, expenses from personal funds being used while on AL must be included in the cost of the travel) and should the funds for your travel be donated, a VA Form 0893 is required, **ALL signature blocks on page 2** must be signed and dated before your foreign travel request memo is signed by all approvers.
- Once you have obtained approval and signatures on your foreign travel request memo, please submit to the Foreign Travel office via email along with all the supporting documents so that it can be reviewed to ensure that VHA Foreign Travel Policy was correctly followed. Once it has been determined that your approval memo follows the policy, the request will be forwarded to Official Passports so that they can release your government passport for travel.

Setting Up Official VA Travel – The Process

When the VA requests Travel for a VA employee, a Travel authorization would be sent to the local Medical Center including the Research Office. The local Medical Center is generally interested in what VA organization will be paying for the Travel. For Travel requested by the VA (generally ORD or VACO), ORD will provide funding to the station upon approval. This type of Travel is generally used for travel to the VA Merit Review Board or other proposal review meetings, ORD-sponsored conferences, and the like. Approval for the Travel should first be

obtained from the traveler's immediate supervisor.

At some stations, the Financial Management Office needs to approve the Travel and have funding source verified, thus some Medical Centers may have a Financial Management Office SharePoint or LEAF request process set up for this. Once approval(s) are obtained, the traveler needs to use the Concur Travel System to input Travel dates, funding source, and to specify mode of transportation (airline, train, or car); reservations can be booked through Duluth Travel in the Concur system (https://cge.concursolutions.com/). Additionally, lodging, any local car rental (if approved), can also be booked. The traveler should set up an account in Concur. Allowed per diem including lodging and meals and incidentals (M&I) rates differ for varying cities and regions of the country and can be obtained from GSA. Lodging expenses over the per diem rate may need to be approved ahead of time and it is possible that the traveler may be responsible for lodging rates exceeding government approved lodging rates. Note: At some facilities the Travel Office will initiate the necessary entries into CONCUR for the employee, based on the information submitted on the Travel Request and Travel Details documents.

It is recommended that sites DO NOT require approval of individual trips by the R&D, Education, or other local committees when the travel is:

- Not using any local VAMC travel funds (e.g., funded by ORD)
- Is an itemized expense in a VA-funded Merit Review or similar award since these expenses have already been approved by the peer review panel and will be paid from the ORD-funded award
- Requiring local approval in these circumstances often leads to needless delay in the process
- However, despite no local VAMC funds being used, the Medical Center may still require the traveler to process the travel authorizations, as is required for all other types of travel.

Having a Point of Contact in the Research Office who has had extensive training with the Concur Travel system is key. Most, if not all, Investigators will not be able to navigate the Concur system except maybe to try to find appropriate air transportation times (even the official contracted airline carrier information can sometimes be daunting). This Point of Contact can be someone in the Budget section of Research Service, or – as may befall many Research Services – the Research Service Administrative Officer or if there is a Center or REAP administrator, that person could also be of valuable assistance in working with Concur. Both generating the Travel authorizations and completing Travel vouchers can be somewhat tricky with the former being more onerous in choosing the correct codes for type of funding source. If you cannot locate a knowledgeable user for assistance in your Research Service office, try contacting your local Travel Office for a recommendation. They typically know staff throughout the Medical Center, who are heavy users and willing to assist the occasional investigator.

If one travels more than twice a year, a government credit card can be secured through the Financial Management Office of the Medical Center to pay for lodging, meals, and out of pocket expenses.

- Government credit cards may revert to $1 credit if not used routinely and prior to Travel, line of credit for the Government credit card needs to be reactivated through the Financial Management Office.
- Government credit cards cannot be used for expenses not incurred for government Travel and must be paid in full upon receipt of the credit card statement.
- *The traveler is responsible for paying all charges that are incurred to this card.*
- Training must be complete to be issued this card. This training will reinforce the

requirement that only the traveler uses the card for official VA travel, and never for any personal use.

- A VA travel card is used to pay for hotel, parking, meals, taxis, and other ground transportation, while traveling on official VA business.
- If you do not have a VA issued travel credit card, then the traveler must use their personal credit card.

Regardless of which card is used (VA Travel credit card or personal), once Travel is completed, expense reports (called Vouchers in CONCUR) should be completed within 5 days of end of Travel.

- Receipts that should be kept are airline or train ticketing receipt, lodging receipt, and local transportation receipts.
- Should the traveler use his/her own vehicle to get to the airport or train station and park his or her car at the airport or train station, mileage verification from home to station and parking receipt is also needed for reimbursement.
- Please note that gratuities will only be reimbursed up to 20%. Anything more than 20% is at the expense of the traveler.
- When using a VA Travel credit card, submitting the expense report (Voucher) in CONCUR allows certain expenses to be paid directly to the issuing bank.
- Any leftover amount can be direct deposited to a personal bank account.
- It is important to separate all the expenditures into the proper categories, as prompted by the system (e.g., hotel taxes are separate from room charges).

SECTION 7 – Research Equipment Inventories

Supply Chain Management (SCM), also sometimes referred to as Logistics Service, and formerly known as Supply or Acquisition and Materials Management (A&MM) Service) is one of the non-clinical support services that assists Research Service in equipment management. The Equipment Inventory Listing, or EIL (formerly, the Consolidated Memorandum Receipt, or CMR), is kept by SCM. Equipment purchased with VA funds is listed on EILs. Equipment can also be donated to the VA and these pieces should also be listed on an EIL. Generally, it is best to have each individual Principal Investigator have his or her own assigned EIL (this requires that they be a VA-paid employee). Otherwise, the ACOS will be responsible for all VA research appropriation purchased equipment placed in individual laboratories and/or offices, as well as common/shared research equipment resources.

The Research Service may have a store of equipment from Investigators who have left the VA. Such pieces of equipment may be placed on a separate EIL under the responsibility of the ACOS, until it is assigned to another investigator's EIL. Research Service may also have administrative equipment or non-laboratory equipment. It is good practice to have a separate EIL for this administrative equipment. Office of Information & Technology (OI&T) is responsible for all computers and data storage devices, printers, etc., purchased with VA IT funding. These pieces of equipment will be on an OIT Equipment Inventory Listing (EIL) and not a Research Service EIL.

Once VA-purchased equipment is received by the Medical Center's warehouse, a Biomedical Engineering check is done (if required). At that time, SCM applies an inventory barcode to the equipment, generally prior to delivery of the equipment to its designated location.

On a required annual basis, all VA-purchased equipment is accounted for by a scanning process. In brief, VA barcodes are placed on each piece of VA purchased equipment or equipment donated to the VA. Additionally, each room where the equipment is kept also has a barcode at the entranceway. The entranceway barcode is first scanned, followed by scanning of each piece of VA equipment within that room. The entranceway barcode is then rescanned upon completion of the scanning of each piece of equipment with a VA barcode. Scanners are returned to SCM for download into their Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) to track all VA equipment.

Old, outmoded, unrepairable, or otherwise unused pieces of equipment should be turned in via a Request, Turn-In, and Receipt for Property or Services, VA Form 2237. This form is also used to report a misplaced and unfound, lost, or stolen piece of equipment.

When non-VA IT equipment purchased by another institution is brought onto a VA station, or put into use on a VA station, the equipment must be first approved by the local Chief Information Officer (CIO) and put into the AEMS/MERS system of the SCM. Generally, when such IT equipment is purchased by a VA Non-Profit Corporation, that VA Non-Profit will donate the IT equipment to the VA so that a proper VA equipment barcode can be obtained. However, circumstances may be different when the equipment is purchased by the academic affiliate.

An affiliate may have its own set of rules that it could loan the equipment to the VA, rather than donating it to the VA, or in some cases would not consider even loaning the equipment to the VA. Should that equipment be needed by a VA investigator to be used at the VA, this will pose a problem to the Investigator who needs the equipment in their research program. In these latter cases, a Memorandum of Understanding between the VA and the affiliate could be generated to have affiliate equipment situated at the VA. An alternative is to work with the local CIO to approve such affiliate equipment to be at the VA, so that the equipment could still be tracked in AEMS/MERS, with an understanding that once the equipment is no longer needed, it can be returned to the affiliate.

Personal equipment brought to or placed in service at the VA also needs approval, depending on the type of equipment. Personal equipment declaration can be made on VA Form 2235. For personal IT equipment, the CIO must be the approving official. SCM may have a separate, non-barcoded sticker to apply to such personal equipment to identify it as being approved to be at the VA.

SECTION 8 – Credentialing Privileging for Research Staff Conducting Human Subjects Research Projects at Your Station

All research staff who are licensed health care professionals permitted by the VA medical facility to provide patient care services independently must be credentialed and privileged (if applicable) as defined in VHA Directive 1100.20 (Credentialing of Healthcare Providers – 09/25/2021) and VHA Directive 1100.21(1) (Privileging-03/02/2023). Licensed healthcare professionals must be credentialed through VetPro. Licensed healthcare professionals must also be privileged if they are also licensed as independent practitioners, such as physicians, dentists, and other health care providers as described in VHA Directive 1100.21(1) and practicing. Only practitioners who are licensed and permitted by the VA medical facility to practice independently may be granted clinical privileges. The following apply to those conducting research:

- Credentialing and privileging are VA Facility specific. A VA employee at one VA Facility who is credentialed (and privileged if applicable) to perform clinical procedures cannot do clinical procedures at another VA Facility without being credentialed (and privileged if applicable) at the other VA Facility.
- A VA employee (or anyone else) cannot rely on the credentialing (and privileging, if applicable) of another VA employee to conduct procedures, regardless of whether it is for research or non-research purposes.
- VA Investigators and VA research team members must hold a VA appointment (VA paid, WOC, or IPA) prior to beginning any research duties and/or contact with patients/participants or analysis of data and/or biospecimens. A VA fee-basis employee does not permit that individual to be a VA study team member.
- Individuals with VA affiliate badges or volunteers cannot conduct VA research.
- Research staff may only perform those activities in a research study that are allowed by the job series to which they were appointed, have the relevant credentials and privileges (if applicable), and are allowed by their functional statement or a separate document describing the duties they can conduct for research if not covered by the functional statement (FS) or job description (JD), such as a research scope of practice (or scope of work). The position description (PD) or functional statement (FS) and performance plan should reflect the duties/activities that may be performed in the research activity. If the PD/FS and performance plan adequately address the duties in the specific study, a separate Research Scope of Practice or Scope of Work (SCOPE) may not be necessary. If not, a SCOPE must be completed. *Note: WOCs may not have a PD or FS so would generally require a SCOPE.*

Research Scope of Practice or Scope of Work

The Research SCOPE is an alternative document to the PD or FS that defines the activities in research, cataloging all duties granted by the PI.
The SCOPE is:

- Updated when new duties are assigned, or others deleted.
- Signed by research staff and PI.
- Documentation that the assignment is appropriate, as it relates to education, experience, and training of individual to perform the assigned duties.

Research staff MUST NOT perform any duties or practices beyond what is allowed in their SCOPE, PD, or FS. For example, if your SCOPE does not list that you are permitted to obtain consent, then you are not permitted to obtain consent. Care should be taken to ensure that research employees without requisite clinical privileges at the VA facility are not practicing medicine without a license. Furthermore, health care providers may not perform activities in research settings that they are not credentialed to perform

in a clinical care setting, even if qualified by training or licensure to do so; if a particular procedure is required in a research study, then the clinical privileges or scope of practice must first be updated to add that function.

Who Needs Credentialing and Clinical Privileging?

VetPro is an Internet-enabled data bank for the credentialing of VHA health care providers that facilitates completion of a uniform, accurate, and complete credentials file. All licensed staff, or those with the ability to obtain a license, must undergo the VetPro credentialing and privileging (if necessary) process before being permitted to utilize their licensure or training to perform research activities. This pertains to MDs, RN, NPs, PAs, LPNs, LCSWs, clinical psychologists, and other licensed personnel regardless of if they have a VA paid, WOC or IPA appointment, who:

- conduct research in direct contact with patients.
- conduct research at a site that has a VA offsite waiver
- NOTE: Foreign medical graduates who are unlicensed in the United States, or those with education allowing for clinical practice — but are not licensed to practice in the United States — do not need to be VetPro'd.

University employees who are conducting the same study at the University are not credentialed and privileged (if applicable) at the VA to enroll subjects; these are not VA subjects, and the activity is not VA research. The University's activities must be overseen by the University's research regulatory review committees and medical staff office for credentialing and privileging (if applicable) for university employees who are healthcare providers. However, if University employees are wishing to come to the VA Facility to recruit VA patients and conduct procedures at the VA, the activity must be done as VA research and the University employees cannot use their university appointment to conduct VA research; these employees must obtain a VA appointment that would permit them to conduct VA research.

Registered Nurses working as Research Nurses

- Must be VetPro'd before engaging in research activities with human subjects
- May perform limited non-patient contact duties while waiting for VetPro if:
    - The VetPro process has been initiated.
    - They have immunizations record verified by Occupational Health Services.
    - They have completed all required TMS trainings.
    - Are listed in the research study staff application to the research regulatory committee as study staff.
    - No shadowing is permitted.
    - Their Scope of Practice, or SCOPE, specifically lists only office duties that do not involve interacting with study subjects (submissions to oversight committees such as IRB, protocol review, or attendance of sponsor meetings). Once VetPro'd, the SCOPE should be changed to reflect engagement in direct patient contact.
    - Access to PHI and research data is allowed in accordance with the approved protocol.

Human Studies Orientation

- While not mandated by national policy, a best practice might be to offer a Human Studies Orientation, or HSO, led by the Research Program (e.g. Human Research Protection Program Staff), to also include meeting with the Research Compliance Officer. This orientation would be separate from the nationally mandated CITI online courses on human subjects research. This HSO should include review of PI responsibilities, research staff responsibilities, and all facility and national policies and procedures that pertain to Human Subjects research.
- All research personnel conducting human subjects research are required to take this orientation.

- All VA PIs, VA Co-Investigators, and Pharm Ds might be required to take HSO if the VA Facility supports it, regardless of if they have direct or indirect human contact. If the VA Facility makes human subjects' orientation a requirement, consideration should also be given to whether all individuals conducting human subjects research must complete the same requirements or whether some individuals, such as those who are analyzing bio-samples or data should have different requirements, such as including an orientation to the local privacy officer or clinical pathology director.

- All VA Facilities with approved research programs are required to have an active Federalwide Assurance (FWA). Please check the OHRP e at Office for Human Research Protections Database (nih.gov) or contact ORD's VA IRB Network Director if there is a question whether a VA Facility has an active FWA.
- If human subjects research activities are occurring at a non-VA site (e.g., University) as part of a collaborative study, the non-VA site must have an active FWA if the research requires IRB review and approval. Please check the OHRP e at Office for Human Research Protections Database (nih.gov) or contact ORD's VA IRB Network Director if there is a question

Many VA facilities with approved research programs have numerous community-based outpatient clinics (CBOCs). These CBOCs are covered under the VA Facility's approved human subjects research program and FWA unless the CBOCs are contract CBOCs. Vet Centers are also covered under a VA Facility's FWA. Contract CBOCs are not covered under a VA Facility's FWA.

SECTION 9 – VA Training Requirements

A designated Research Administration employee (in some stations, it is the Administrative Officer) is the usual point of contact for information on becoming authorized to conduct VA research at the facility. This administrator manages the authorization process and assigns courses and forms. The courses and forms are dependent upon what the research duties are, if there is direct or indirect contact with human subjects, if there are biological specimens, and if the personnel are licensed. Please consult the ORD web page for specific information on the requirement Research Education and Training (va.gov)

All Research Personnel Conducting Human Subjects Research

- Collaborative Institutional Training Initiative (CITI) Biosafety for personnel that handle biological specimens (phlebotomy/CSC lab) – annually.
- CITI VA Human Research Modules – Initial Training
- CITI VA Human Research Modules – Refresher training required every 3 years.
    1. Biomed Refresher 2 – History and Ethical Principles (ID: 511) – required.
    2. Biomed Refresher 3 – History and Ethical Principles – Research vs. Practice (ID: 993) – required.
    3. Any six from the 30 refresher modules listed in CITI.
    4. GCP Training (CSP and CSR&D Clinical Trials as well as some industry sponsors require this)

- Blood-borne Pathogens and Tuberculosis – *when working directly with subjects or in a clinical setting*, sites may use the TMS module, a local training module, or choose to accept equivalent training from the affiliate.
- Note: VA Research Programs can integrate their training with the Affiliates CITI training. Further information can be found at Researcher Training (va.gov)

Personnel Conducting Animal Research:

- Working with the VA IACUC CITI module, every 3 years
- Species-specific CITI modules, as applicable to their work – every 3 years
- IACUC members must take the CITI Essentials for IACUC members – every 3 years.
- Waste and Anesthetic Gas Training - as needed.
- Additional optional training models can be found under Required training for staff involved in the use of animals in research (va.gov). For IACUC members, the CVMO Office has put together a compilations of various training scenarios that are excellent.

Personnel Conducting Laboratory Research

- Laboratory safety training as determined by local policy. This may be either by computerized course training or in-person training or both.
- Specialized training for radioisotopes or other hazards as determined by local policy.
- Information can be found at Biosafety & Biosecurity Program (va.gov)

Additional Training Required of all Working in VA Research

- VA Privacy and Information Security and Rules of Behavior
- VHA Privacy and HIPAA (when working with PHI or III)
- Government Ethics
- Technology Transfer Program (PIs only)
- Local sites may require additional training modules for designated employees.

SECTION 10 – General Administrative Management

Some Administrative Officers have other titles (especially at larger research programs), "Director of Research Operations," or "Business Manager", which reflects an important characteristic of the position. Administrative Officers may or may not have a scientific background, but their primary function is to ensure the optimal function of the Research Service. Whereas the ACOS is the head of the Research Service, the AO is responsible for the day-to-day operations of the program.

Additionally, many AOs have such duties as HRPP Officer or Safety Coordinator. As mentioned at the start, there is no "one size fits all" in the world of Research AOs. Regardless of your other responsibilities and titles, because you possess the right mix of skills and experiences to best help and advance the research program at your facility.

Help Resolve Any Issues That Arise

One reason why AOs are so busy is because they are the "go to" individuals for any problem that arises at their facility. If you have an open-door policy, you will need to be able to handle frequent interruptions. Your ACOS may have many other duties, including clinical care, university commitments, lab supervision, executive management level meetings, and so on. This will force the ACOS to be out of the Research Office, from time to time.

You do not need to be the expert on everything, but one skill that is important to develop – *as soon as possible* – is the knowledge of who to go to for what. Drilling down deeper into this concept, you need to be aware of the pitfalls. You may find that some people steer you in the wrong direction, give you partial information, or, otherwise, complicate or compromise your ability to resolve a problem. You will build your team of trustworthy agents, who are willing and able to readily resolve whatever problems arise. It helps to build commitment by continually reinforcing the value of research to Veterans among your co-workers across departments.

SOPs

SOPs are written based on local facility, central office, and ORO requirements, as well as on local laws. They describe how the research program operates.

At many facilities, the AO writes the SOPs, but some SOPs might have some technical aspects to them that are beyond the AOs training. In this case, others may need to be called in to help. At other facilities, the committees are responsible for creating the SOP, and they may form ad hoc groups to complete the task.

No matter who writes the SOPs for research, they will be carefully examined by ORO, and the accrediting organizations and any deficiencies will be noted so that they can be updated and brought into compliance. One bit of advice in writing SOPs is to not be so restrictive on elements of the SOP that it would be difficult for the facility to keep compliant with the SOP.

Committees

The AO and/or ACOS (or delegee in larger programs) usually serve as an *ex officio*, non-voting member on all the Research oversight committees, such as:

- Research and Development Committee (R&DC) – premier oversight body; sometimes acts as basic science review group (*VHA Directive 1200.01*)
- Institutional Review Board (IRB) – human subjects research (*VHA Directive 1200.05*)
- Institutional Animal Care and Use Committee (IACUC) – animal research (*VHA Handbook 1200.07*)

- Subcommittee on Research Safety and Security (SRSS) *(VHA Directive 1200.08)*
- Institutional Biosafety Committee (IBC) – reviews research involving recombinant DNA.
- Basic Science Review Board – neither animal nor human research (established as some facilities, some may use the SRSS for this function, others the R&DC)

It is important that the AO understand that their involvement is to help the committee members with their assessments, and not to drive towards a decision of their liking. The AO, like the RCO, should act as an information provider and reluctant advisor in the committee setting. The AO will often report a status update to various committees on issues impacting their committee or the research program. The RCO and AO should work together to help the committees have all the information they need to make accurate decisions and determinations.

The ACOS serves as the non-voting "Executive Secretary" of the R&D Committee. In this capacity, the ACOS can brief the R&D Committee on such items as the ORD Field Conference Call, the Field Research Advisory Committee (FRAC) meetings from minutes received from those meetings and other goings-on in ORD. In addition, the ACOS has specific responsibilities outlined in the Office of Research Oversight Facility Director's Annual Certification that can be communicated to the R&D Committee. These items include:

- Ensuring that all requests for research WOC appointments are appropriately justified and the appointments comply with all applicable research, human resources management, and other VA policies.

The ACOS may also use the R&D Committee venue to have short presentations of various educational topics such as committee member responsibilities or responsibilities of Principal Investigators set by either ORD and/or the local level.

The AO and ACOS usually also serve on other committees (potentially in a voting capacity) which may be established such as:

- Research Space Committee
- Research Budget or Finance Committee
- Research Security Committee.

The AO may also be appointed to a variety of medical center committees due to the impact those committees may have on research operations or vice versa. Some medical center committees that may require AO involvement are:

- Environment of Care
- Green Environmental Management Systems (GEMS)
- Administrative Officer Council
- Facility Space Committee

It is important to use these opportunities to build relationships with staff members from different departments, throughout the medical center. You can call on these individuals to assist you in a variety of situations. An additional "bonus" of these relationships is having contacts, outside of research, that, should the need arise, can assist you.

Customer Service

The Research Office serves a variety of "customers."

Principal Investigators and their staff come to the administrative office to process paperwork, obtain information, seek help and guidance, as well as to resolve problems. They usually do not schedule

appointments in advance; they come as time permits.

With facility departments, such as IT, Facilities Management (Engineering), Financial Management (Fiscal), Environmental Management (Housekeeping), Environmental Health and Safety (EH&S), and HR, the Research Administrative Office is the central entity in the struggle to get things done (as well as interfacing with those services). Occasionally, there are inspections or reports that must be fulfilled – and need the cooperation of research to do so. It is then, *they* become our customers, or we become their customers.

Much like the front desk at a hotel, a myriad of people – most unannounced – come to us needing some sort of assistance. It is important to create a friendly, competent, and professional office environment.

New Staff

When new staff are appointed to the Research Office, the AO or designee is responsible for ensuring that the person is properly vetted and if necessary credentialed, has a Scope of Practice or description of duties, and is appropriately tied to a laboratory, project, or administrative entity. The research office will assist in obtaining that person's office or desk space, including a telephone, IT equipment, supplies, badge, access to IT systems, and orientation. Depending on your location, you may need several weeks' lead time to set up a new employee with needed resources.

As stated earlier in this document, PIs are responsible for their new staff members' orientation, but may need assistance from the Research Office for some additional elements.

PIV Badges

The Personal Identification Verification, or PIV badge features an embedded gold microchip that contains information about the badge owner. The process for initial hires is managed by HR and includes getting a VA email address and having the person setup in the PIV portal. After completing this process, the person is ready to be finalized in the system by the Badging Office (depending on the station, it could be HR or Police Service), and is issued a badge. This process must be coordinated with HR, so that security check clearance is underway before the badge is issued.

Service Needs

The AO can also be an office manager, ensuring that the Research Office has the resources it needs in the way of personnel, space, furniture, copy machines, printers, telephones, audio/visual equipment, and supplies. Typically, all these items should be procured through the local VA facility, as these items are not specific to a research study.

The AO is involved in the planning and management of the common areas within research areas, including clinical, lab, and VMU for furnishings and common equipment. The AO often assists researchers, helping them find the items they need for their research areas, subject to the AO's expertise.

Staff Meetings

It is a good practice to conduct regular staff meetings for research administration staff. You may or may not want to include the staff of the VA Research non-profit. Your ACOS may want to participate or even lead the meetings. This is a good opportunity to share news from the facility, update staff on recent events, clarify issues that have become "confused", as well as share information obtained at training and discuss new policies.

Be careful not to let these meetings become forums for public attacks on any one staff member, as these issues should be handled in private and between the people involved.

Also, your staff will appreciate it if you keep the meetings organized and time sensitive.

Researcher Communication and Meetings

AOs should have ways to communicate with different groups of the research community. You may set up an email distribution list for all research personnel, research investigators, or other important subgroups that you need to reach for important notifications. This can be done through IT with a network distribution list, or you can create your own distribution list in MS Outlook Contacts™.

It is also a good idea to have regular meetings with researchers. Some of these meetings may be scientific in nature – the sharing of ideas, creating a spirit of collegiality and collaboration. These "meetings" can also be virtual with a periodic Newsletter or other type of electronic communications sent out on important information items for Investigators and their research staff.

Other meetings may be regarding new regulations or changes to SOPs. Meetings could be targeted to research coordinators, research assistants, lab techs, PIs or any combination of these groups depending on the need.

Research Week Event Planning and Coordination

Every year ORD announces Research Week, usually in April or May. ORD strongly encourages each research program in the field to have its own local events and invite the local community and leadership to the event.

An event like this might have the following agenda at your facility:

- Poster presentations
- Leadership Welcome
    - Director
    - Chief of Staff
    - ACOS
- Veteran Panel
    - Veteran experience with Research
- Keynote Speaker
- Q&A
- Food & Beverage/Poster Review

You should coordinate your event with your facility Director, Chief of Staff, and local Public Relations Coordinator. Have the materials that are sent to you from ORD posted throughout the medical center.

Research Space

An essential infrastructure component of a successful and vibrant research program is the procurement of sufficient research space to support the various types of ongoing research activities. A rational mechanism of space assignment, space renovations, assessment of the quality of research space, and the review of space usage will facilitate the successful accomplishment of research projects and enable for the growth of research programs that will lead to the enhancement of productivity and recognition of the research enterprise.

Assignment and Review of Space

All space within the confines of the Medical Center belongs to the Institution, and its purpose and use will be designated by the Director of the Medical Center. The Medical Center may have a Space and Resources Planning Committee that may have responsibility for research space. In some Medical Centers, Research Service is granted the ability to allocate space 1) to individual qualifying Investigators; 2) to groups of qualifying Investigators with common interests forming a research unit; 3) for core facilities as designated by Research Service; 4) for the use by Research Service that would best serve the interests of the Service, which may include space allocation for properly executed Sharing Agreements

benefiting Research at the Medical Center. If Research Service is delegated to handle Research space matters, there may be a Research Space Committee that functions to distribute and review space, or the R&D Committee may serve in that function in the absence of a separate Research Space Committee, or in other instances, the ACOS may serve as arbiter of space distribution and review. In cases where space is assigned to a Health Services or Rehabilitation Research Center, local policy may delegate authority to the Center for space distribution for investigators who are members of the Center.

The process for research space assignment should be transparent and formalized in an SOP, with criteria for space assignment, review, and renovation that are clearly delineated and prioritized. In addition, it is advisable to have a formal application form for all space requests, with sections that allow for a thorough description of the type of space needed (e.g. wet-lab, animal testing, office, interview rooms, etc.), the infrastructure requirements (e.g. fume hoods, biosafety cabinets, cold rooms, etc.), current and pending funding held by the investigator, and a list of employees that would occupy the space, and how many hours/week they are onsite.

The space assigned to an Investigator will in general be proportional to the amount of funding support or number of funded PIs who can share space with a similar research topic, however, the need must be justified. The following criteria could be considered in space allocation:

1. **Research Funding**
    a. Research programs funded by VA Merit Review Award, or similar VA funding.
    b. Peer-reviewed research with high priority or relevance to the care of Veterans supported by extramural funds only and conducted by an Investigator who is eligible for VA funding.
    c. Non-peer reviewed research supported by extramural funding with high priority or relevance to the care of Veterans.
2. **Common resource research activities** (e.g., use of equipment, research techniques, or focused interests as established in a formal Core Facility or other arrangement with several investigators).
3. **Productivity:** This will be judged by publication of substantive papers in critically reviewed journals. It is recognized that mere numbers of publications will not necessarily establish a high degree of priority, but rather, the significance of the work (as evaluated by ad hoc reviewers, if necessary, as well as the professional stature of the journals).
4. **Support for Clinical Recruitment or Retention** of critical specialty care clinicians. In such cases, space may be assigned for a period of time to help in establishing a funded laboratory for a new recruit or bridging an established investigator to ensure retention of their critical clinical expertise.

Considerations other than outright assignment of Research space, but having space “loaned”, could also be considered in cases such as:

1. Newly recruited Investigators who have no funds, but are eligible for VA funds, and have applied for VA funding, or are in the process of doing so.
2. Temporary expansions in space for ongoing programs.
3. Research programs which are not funded but are being performed by VA personnel who have been determined clinically indispensable.
4. Programs that support important clinical functions.

Generally, space is committed to an Investigator for the length of the funding of the specific program. Career Development Awardees (whatever the source of funding) are usually housed in space of their mentor(s). Career Development Awardees transitioning from trainee status to independent status can be “loaned” space until it is deemed by the R&D Committee that independent funding for a research program has been established.

Office space for Clinician Investigators/Non-Clinician Investigators may be scarce, depending on the facility. However, it should be noted that some research programs, such as health services research and clinical research highly depend on office space to carry out the research. Careful consideration should be given when there is thought to convert "wet" laboratory space to office space, unless the need of emerging programs requiring office type research space is a high priority.

Review of research space is suggested to be conducted on an annual basis. Useable research space can be reallocated. In addition, the following considerations can be considered (not necessarily in the order of importance):

1. Value of the program and Investigator to the VA
2. Impact of space reallocation on other Investigators
3. Immediate need for reallocation of part or all of the assigned space (it is not productive to remove space from an investigator seeking to re-establish funding if that space will not be immediately reassigned and remain in productive use).
4. Impact on collaborations, core facilities, equipment, etc.
5. Personnel versus equipment requirements of the project
6. RDIS II Report of most recent reported research expenditures of the investigator
7. History of grant/contract funding and proposal submission. Investigators without currently funded grants for a pre-determined period (e.g., 2 or 3 or more years) since their last funding period could be in jeopardy of having space reclaimed. Investigators without grant funding for a predetermined period, but who have continued to submit research proposals for funding consideration may be loaned space or could share the present space with other Investigators.
8. Publication history
9. History of having non-VA grants/contracts administered through the VA non-profit corporations may be given preference for VA research space over affiliate-administered funding which is discounted in the Research VERA allocation.

When space needs to be reassigned from one Investigator to another, mechanism(s) should be put in place for appeal of the space reassignment should the Investigator losing assigned research space have a valid reason for continuing to be assigned space.

Repairs and Renovations

The routine maintenance of electrical, plumbing, air-conditioning, and heating repairs are to be directed through the ACOS or Administrative Officer or other appointed Research Service employee responsible for work orders. Requests for research space renovations (e.g. construction, new wiring, new plumbing, installation of lab benches, etc.) should be detailed in memorandum form addressed to the Research Space Committee (if established), the R&D Committee or ACOS. The following information is suggested to be included in the request: a) type and extent of renovations, b) purpose of renovations and/or justification of renovation, c) Investigator affiliation and time commitment to the Medical Center (i.e., VA, University, WOC, percent VA time, etc.), d) estimated cost of renovations, e) whether renovations are to be done by independent contractor (e.g. funded by NPC or affiliate) or by VA Facilities Management Service and/or VA-delegated contracting service, f) if current non-VA grants/contracts are administered by VA non-profit corporations.

1. For renovations to be financed by the NPC or affiliate and performed by private contractor, full concurrence of Facilities Management Service (Engineering) still must be obtained.
2. For renovations to be funded by the Medical Center (e.g. use of Research VERA or special project funds available to the facility for the renovations), projects should be prioritized by the R&D Committee or ACOS with input as necessary from the Subcommittee for Research Safety and Security (SRSS) and the Institutional Animal Care and Use Committee (IACUC), according to

the following suggested guidelines:

a. Renovations necessary for safety, security and/or health issues deemed urgent by the SRSS, IACUC and/or the Medical Center, especially renovations required for continued accreditation.
b. Research core facilities.
c. Faculty recruitments.
d. Investigator group renovations that would enable close collaborations.

3. Information regarding prioritization of renovation projects should be made available to all Investigators. Follow-up of progress of approved renovations can be done through reports given by the Projects Section, Facilities Management and/or Maintenance and Operations, Facilities Management.

In general, renovations or the scope of a project that falls outside of the Maintenance and Operations Office of Facilities Management is delegated to the Projects section of Facilities Management. These projects could be Non-Recurrent Maintenance projects, Minor Construction projects, or rarely, Major Construction projects.

Oversight of Construction and Upgrade Projects

From time to time, your facility may receive funds for construction or upgrade projects that involve research areas. The ACOS and/or AO will be an important part of the planning and coordination of these projects, as they have knowledge of the researchers' needs that surpasses that of any of the contractors or engineering liaisons, and it is important to help them understand those needs.

Communication during construction and upgrade projects is very important. The AO or designee will be the point of contact for the contractors, and engineering liaison for any issues that come up, so that you can forward any information that the researchers might require. (The researchers should know to notify the AO, if they have any problems or concerns.)

The involvement of the AO and R&D office is critical during construction and upgrades, especially when standard services are going to be electively terminated. It is not uncommon for engineering professionals in the HVAC, plumbing, or electrical shops to coordinate tests or upgrades of their systems to minimize or eliminate any negative effects from a planned utility system shutdown. Sharing this information with researchers in advance is essential.

Leased Space, and Offsite Waivers

Should research space not be available on the VA site, consideration can be given to leasing space to perform research (perhaps more facile for research needing office space). For example, a number of VA facilities have lease agreements with their academic affiliate for wet lab research space that is not available at the Medical Center. Leased space should also be integrated into the research space assignment and review policy and procedures.

In other cases, VA-funded (e.g. Merit) research might occur with approval from ORD under an offsite waiver in the investigator's assigned space at the affiliate university, due to need for unique equipment/facilities, or lack of available space at the Medical Center.

General Oversight of Research Lab Areas and Other Odds and Ends

The Administrative Officer is usually an important figurehead for management of the research lab area. It is a good practice for the AO to walk through the lab areas regularly and check in with lab staff to ensure that everything is going smoothly. The responsibilities associated with lab security can also be assessed while out in the lab area. The AO should be knowledgeable of basic lab safety and security criteria and help identify potential issues before they become a problem or are cited in an inspection. They should be

able to guide lab staff to appropriate people for assistance outside their own expertise. The AO also should understand the needs of the lab area and help plan for future needs.

In cases where the Research Program does not have its own Research Safety Officer, the AO should also have a basic understanding of the Biosafety in Microbiological and Biomedical Laboratories document (BMBL), which can be found at Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratories.

Enter Work Orders to Engineering

Your facility will have a system in place to notify Engineering of issues that require attention. Anyone with access to Maximo, or whatever system the facility uses, can enter a work order to the Engineering department. The AO is usually the work order approver.

Many researchers would rather just call the AO, inform them of the problem and have them take it from there. This has its advantages in ensuring that the work order is properly assessed for need and prioritization prior to being entered into the system. It is important to get as much detailed information, as possible, so that you can convey the problem properly to Engineering. Therefore, it is essential to become familiar with the local work order submission requirements, so you can submit complete work orders, and insure the prompt correction of the problem.

Engineering should provide Research with contact numbers for emergencies. Off-hour emergencies may be handled through the Medical Center Police if Engineering does not have its own off-hour coverage in place.

Minor issues – like fixing a light that has burned out or replacing a broken ceiling tile – are sometimes handled by a "Cart Man", or person who roams the facility repairing minor fixes.

Examples Engineering Work Orders:

- Install a rack for gas cylinders.
- The eye wash is starting to come off the wall.
- A new piece of equipment needs to be installed with appropriate power supply.
- There is a slow leak in the restroom.

Involvement in Emergency Preparedness Plan

The Research Service should have its own emergency preparedness plan, and the AO should be a part of its creation and maintenance. It is probably good practice to integrate the Research Emergency Preparedness Plan into the Medical Center's overall Emergency Preparedness Plan. This can be done by working with the Medical Center's staff responsible for Emergency Management; many times, the Environmental Health and Safety (EH&S) Service takes the lead with the Facility's Emergency Preparedness. It is important that this information be shared with researchers who work in dedicated research areas, so that they know what to do and where to go in an emergency.

If you have an animal facility you will have a VMU Emergency plan since there are requirements for the proper handling of animals in an emergency, this VMU plan also should be integrated into the overall Research Service Emergency Preparedness Plan.

It is the responsibility of the AO or other designee to ensure that emergency drills are conducted. These drills can occur at the direction of the facility Safety Office, Subcommittee on Research Safety & Security, or the Research and Development Committee.

It is essential that the PI or Research Service Staff immediately orient new staff members to all applicable safety, security, and emergency management policies and procedures, including a tour of the areas where they will be working, the location of safety equipment (e.g. fire extinguishers, eye wash stations, emergency showers) and emergency egress pathways.

Emergency Cascade Plan

Every service at your facility has an Emergency Cascade Plan. This is a document that lists all the members of the service with emergency contact information. The person at the top of the list calls the next person down on the list, that person calls the person below them, and so forth. For Research Service, the cascade launches from the ACOS, who will provide any information and instructions. The ACOS (and alternate, which may be the AO or Deputy ACOS) is in turn listed on the facility Emergency Cascade Plan to ensure the proper transmission of emergency information to Research Service. The Emergency Cascade Plan should be updated, as needed, and kept current. You may need to send a copy to the facility Safety Office, or other designee. There are commercial companies that assist to organize the cascade to make it easy to "spread the word."

Additionally, it is helpful to send an electronic copy of this document to your personal email address, so you have access to the information *even* if you are away from home or the facility.

Facility Emergency Response Team

Usually, the ACOS is part of the facility emergency response team. Sometimes, the AO is part of this team as well. Your local facility will inform you regarding what is expected of you and the Research Service team, in the case of emergencies.

Key Requests

The Research Office should have a Security Plan in place to control access to research areas. Sometimes researchers change location, or when a new researcher comes on board, they will need keys or access badges to their areas. The AO (or the AO may delegate to someone in the research office) may be the person to approve and make the request to Service responsible for issuing keys (in a number of facilities this may be the Police Service). There may be research training requirements that need to be met before keys should be issued.

Sponsoring key requests for WOC employees may be a hurdle if the sponsor is not a VA-paid employee. This may be true with a WOC Principal Investigator located at the VA who also has WOC employees in his/her research program. In those cases, another VA-paid Investigator may want to sponsor the key request especially if the WOC researcher is also collaborating with the VA-paid investigator. In some cases, the Research Office may need to sponsor the key. If that is the procedure followed, the Research Office needs a mechanism to track which WOCs have been issued keys so that returning keys can be made part of the clearance process when WOCs leave the Service.

The AO, as well as the ACOS, should have a master key to all research areas.

Hood Certification

Fume hoods and biological safety cabinets need to be certified at least annually. Safety cabinets in BSL3 facilities must be certified semi-annually. The AO or the Research Safety Coordinator, through the SRSS, may be responsible for ensuring that hoods are properly certified. It is also possible that this function has been assigned or delegated to local engineering personnel or the Industrial Hygienist, so it is very important that you confirm the local process for hood certification.

SECTION 11 – Information Technology (IT)

Perhaps one of the more complex and complicated aspects of administering a research program is dealing with items related to Information Technology (IT).

What defines Funding for IT related purchases

VA Directive 6008, "Acquisition and Management of VA Information Technology Resources" establishes policy for the funding of development, acquisition, operations and management of IT, IT-related and other assets and resources related to IT. The directive defines what VA IT or non-VA IT assets can be purchased with what funding source. While c omputers, other data storage devices and software may be purchased through the university affiliate, the VA non-profit corporation, or other institutions or entities that may support VA research, there are requirements for VA data security and inventory management (see below) that you should discuss locally with OIT to ensure that the items may be placed into service at your VA.

Computers and Software for Research

Computers for Research Service, and those computers for Investigators and research staff that are to be connected to the VA network should be obtained from the local OIT Service. Your local IT department is responsible for fulfilling all general IT needs of the Research Department. Standard PCs, printers, network connections, and most standard software (Operating System, Office Productivity software (such as MS Outlook®, Word®, Excel®, and PowerPoint®,) are to be provided by the facility IT department. All other software may be found on the TRM approved software list, including some open-source software for research; software on the TRM list can be requested of VA OIT.

There are a limited number of other bulk licenses for software like VISIO and Adobe® Acrobat which are requested through and tracked by OIT. Finally, certain services for software may be purchase with VA research funds: Software as a Service (SaaS).

Other software that is needed for research cannot at this time be purchased with VA appropriated research funds (e.g., statistical, image analysis). Such software may be purchased with Affiliate or NPC grant funds, but the version must be compliant with VA regulations (e.g., the commercial version not the education version), and must be cleared in advance by OIT.

If the standard VA provided computers do not meet the needs of research, such needed computers cannot at this time be purchased with VA research funds (see however special case below of Research Scientific Computing Devices [RSCD]). If you discuss ahead of time with local OIT and receive concurrence, investigators may be able to purchase with Affiliate or NPC grant funds but must get VA baseline security software to be added to the VA network (VLAN) and be placed into VA inventory (see IT/RCSD Inventory Management below).

Flash drives or external hard drives may be provided by VA OIT or purchased with non-OIT funds (VA research funds, Affiliate or NPC grant funds). Regardless of fund source, the drives must meet VA security standards and inventory requirements as detailed in this guidance. A current listing of compliant devices is found at FIPS 140-2 Validated Removable Storage Devices.

IT Equipment Requests

For basic IT Services (e.g., desktops/laptops, printers, wireless cards, smartphones, help desk and

telecommunications support) OIT's yourIT provides the capability to submit a request for these types of IT equipment requests. Through this submission process, your local OIT department will provide basic IT Services (e.g., standard PCs and computing equipment, printers, portable/removable storage devices, and monitors) for general, networked, non-scientific use. The IT department at your facility will advise you of any additional processes for submitting new IT Equipment and/or replacement requests.

Research Scientific Computing Devices (RSCD)

Computers that operate research equipment are considered part of that equipment and can be purchased with research funds. These types of equipment are classified as a Research Scientific Computing Device (RSCD). RSCDs are usually not loaded with VA security features or encryption as this would interfere with the software running the equipment. OIS has developed an enterprise process for securely connecting a RSCD to the VA Network for appropriate research purposes. Researchers and Research Staff are encouraged and recommended to review the requirements for submitting a RSCD for connection to the VA Network through the Enterprise Risk Analysis (ERA) process at ERA Portal. Additional training on the process is available at the RSCD ERA Training Resource Guide. Through the ERA process, RSCDs will be logically isolated on the VA Network through a Device Isolation Architecture (e.g., Virtual Local Area Network (VLAN)).

IT/RSCD Inventory Management

All equipment and computers maintained in VA facilities are required to be inventoried, even if the VA does not own the equipment. Research devices and/or RSCDs are often donated or acquired using non-VA OIT funds and are supported by the scientific team making the acquisition. This support may include patches to operating system, upgrades to firmware or application layers, and management of data including backup and restoration. The use of personally owned information systems on-site to perform assigned official duties is discouraged and must be approved by the Area Manager/System Owner or designee.

VA Handbook 7002 states, "The VA CIO is responsible, at the Department level, for ensuring the integrity and security of VA's IT assets, including physical inventory as well as data protection and the sanitization of data when IT resources are retired from service."

VA Handbook 7002 states, "Equipment owned by an affiliated institution, or purchased by such institution from grant funds, used by a VA investigator in a research project at a VA installation will be accounted for in the appropriate VA property accountability system, regardless of cost of the equipment."

- OIT maintains the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) as well as MAXIMO for this purpose.
- OIT Owned: All hardware in this basic & advanced infrastructure stack should be owned by OIT and recorded in an Equipment Inventory List (EIL) Managed by the local area manager. Since all the Lifecycle Management funds (money available to replace the oldest hardware first according to industry accepted standards) is distributed by OIT based on information on equipment age from the EIL.
- Equipment purchased by ORD using funds from their non-profit corporation (NPC) should be donated to the VA and listed on the OIT EIL for that medical center. (See discussion of "Scientific computing" below for exceptions to this practice.
- Equipment not owned by the VA and purchased by an affiliate institution and used at VHA facilities need to be entered into the EIL.
    - Note: equipment on an EIL does not indicate VA Ownership.
- Annually, a physical inventory of all nonexpendable accountable property and designated

sensitive items will be conducted. (VA Handbook 7002 8.5).

- Inventory Best Practices are summarized in an OIT Webinar slide deck

It would be preferred to involve the VAMC clinical engineering staff in support of many RSCDs or for research to obtain a support contract for their maintenance, troubleshooting, and problem fixing. Examples such as large neuroimaging research centers may require considerable clinical engineering support for routine maintenance, troubleshooting, and storage/backup of data.

VA-Compliant Data Storage, Transfer and Sharing Options

There are several mechanisms for data sharing and transfer, with guidance linked that include size of data that can be transferred. SharePoint and OneDrive can store and share data with VA internal customers. VA Box.Com can share with external collaborators after they get an ID.Me account). A detailed report on available VA data storage and sharing options can be found here, and a helpful summary document is available also to share with investigators, the summary document includes a link to the larger report for those who want more detail VA Data Storage Transfer Sharing and Records Control One-Pager (sharepoint.com)).

VA Research Computational/Analytics Applications and Platforms

The report referenced above also provides a fairly detailed comparative overview of the various VA computational and analytics platforms developed in recent years, including VINCI, GenISIS, and a number of others, and a one page summary (with embedded link to full report) suitable for sharing with investigators is available.

VHA Research and Development IT/Informatics Guidance FAQs

ORD disseminates a FAQ annually to the research community. This FAQ contains additional guidance around the acquisition and management of VA Information Technology Resources, IT Budgeting, requesting VA OIT services, scientific computing, statistical analysis, and research analytical tools. It also includes guidance around inventory management and Enterprise Risk Analysis (ERA) process requirements for Research Scientific Computing Devices (RSCD). The FAQ can be found at ORD Research IT FAQs and Guidance. Additional FAQ and other Research IT/information security guidance resources can be obtained through Office of Research Reviews (ORR, see below). .

Remote Access to the VA Network

Researchers may work off the VA site yet need access to the VA network where VA research data or other research-related documents, images, etc., are stored. To request remote access to VA systems, go to the Remote Access Portal and complete the application.

Office of Research Reviews

The Office of Research Reviews (ORR) consults with stakeholders across the VA enterprise participating in research programs, providing guidance in complying with research information security policy. The ORR Team consists of cybersecurity specialists, Subject Matter Experts, and enterprise Information System Security Officers who are responsible for responding to enterprise cybersecurity requests and needs of VHA stakeholders through the development of research information security guidelines, procedures, training, and policy. O R R prioritizes the development of enterprise cybersecurity processes and the adoption of approved technologies that align with the business considerations and objectives of the Office of Research & Development (ORD) and the Office of Research Oversight (ORO). A link to ORR guidance resources and FAQ can be located on the Guidance Resource Portal. ORR can also be reached via oissdcdorrresearchreviews@va.gov, and consultations can be requested via the VHA Regulatory Research Cybersecurity Guidance ServiceNow Catalog in “yourIT” ServiceNow.

SECTION 12 – Project Management

As AO, you will find that some of your work will entail executing a multi-faceted project involving several people performing various tasks over time… project management. It is helpful to have a grasp on a system that will help ensure that the project you are leading is progressing as needed. VA Acquisition Academy offers courses in project management leading to certification. Information is available at: www.acquisitionacademy.va.gov

Compliance Issues

For example, after an inspection, a compliance finding may have been identified that requires researchers, engineering and/or fiscal to perform tasks. You will need to track everyone's performance in correcting the finding, as to report to the oversight body within the given timeframe. Within some research programs the RCO handles these matters; at others, it is the AO or designee.

Tracking Dates

There are many deadlines within the VA and the AO needs to be on top of them and enable enough time for others to complete their portion of the project. A general calendar of some of these items can be found in the Calendar at the end of the Manual.

Liaison for Construction and Engineering Projects

As mentioned earlier, the AO or designee will be the primary point of contact on construction and engineering projects involving research areas. The AO needs to be made aware of the timeline and scope of these projects with frequent updates regarding delays, problems, or completion. The AO should communicate important and relevant information to researchers.

Paperwork Reduction Act

The Paperwork Reduction Act defines when collections of information require OMB clearance. VA Directive 6309: Collection of Information and VA Handbook 6309: Collections of Information Procedures describes VA's policies for compliance with the Paperwork Reduction Act. VA Handbook 6309 describes items considered not be collections that should generally not be information defined under the Paperwork Reduction Act, collections of information not subject to the Paperwork Reduction Act, and collections of information subject to the Paperwork Reduction Act. All collections of information do not require OMB clearance, but when the collection of information requires OMB clearance, it must be obtained. For example, all qualitative activities (both research and non-research) do not require OMB clearance when the information is not obtained by means of identical questions or identical reporting, recordkeeping, or disclosure requirements. For those that do, obtaining clearance is required. For ORD funded studies, such as the HSR&D and CSP studies, the funding service has a process for evaluating clearance and works with the VHA PRA office for the studies they fund when the collection of information requires OMB clearance. When there is an issue of whether the activity requires OMB clearance, whether it be a research or non-research activity, the query should go to the VHA PRA liaison at the VHA PRA shared mailbox at VHACOPRA@va.gov.

SECTION 13 – Compliance

There are many regulations affecting VA research in the form of VHA Directives, Handbooks, Policies, Federal, State, and local laws as well as accreditation organizations. Oversight and monitoring of compliance with these regulations is primarily the responsibility of the Research Compliance Officer (RCO) but a close relationship with the ACOS, the AO, and the R&D Committee and its subcommittees is essential.

All repetitive activities, including regulatory requirements should be documented in local policies or SOPs as outside regulatory agencies and accreditation review teams look for the local SOPs to see if statements made within the SOPs are being adhered to. The Research Service, R&D Committee and its subcommittees are responsible for creating these local SOPs, reviewing all projects to ensure they are compliant before approval to initiate the research is granted, and reviewing instances of potential noncompliance to make determinations on required remediation of confirmed noncompliance. Furthermore, it is the responsibility of the Research Service that all investigators and research staff are properly and fully trained in the facility SOPs.

ORO

The Office of Research Oversight –(ORO) is the primary internal VA entity that ensures that every VA Research program is compliant with regulations. ORO reports to the Under Secretary for Health.

ORO has different subject matter groups:

- Research Safety & Animal Welfare
- Policy & Education
- Human Research Protections
- Review Management and Integrity
- Research Information Security
- Informatics & Data Analysis

Your MCD submits a report to ORO every year: The Facility Director's Certification of Research Oversight. Instructions are posted on ORO's website. Information to complete the form will come from various sources including ePROMISe, Committee records, and audit records held by the Research Compliance Officer. As such the RCO and the Research Office will typically work together in completing the annual report.

ORO also conducts site visits General Information - Office of Research Oversight (va.gov). Their goals are:

1. Conduct a standardized review of each facility's infrastructure for protecting human subjects, investigators, and animals in research.
2. Regularly scheduled Comprehensive Program Reviews (CPRs) (every 5th year) Virtual and Limited Onsite Components
3. Follow-up reviews based on Prioritized Area(s) of Vulnerability
4. Focused Onsite Reviews
5. Onsite Technical Assistance Reviews
6. Remote Follow-up Reviews
7. Continue For-Cause Onsite Reviews, as needed.

ORO also receives reports of non-compliance and opens cases as needed to track action plans and proper closure of the noncompliance. ORO has developed many checklists that help identify and assess local compliance with requirements. They may be found at

https://www.va.gov/ORO/orochecklists.asp. Many other entities will inspect or survey the program for compliance with their regulations (e.g., FDA, AAALAC, OSHA, ITOC, OIG, etc.).

RCO

The Research Compliance Officer (RCO) is appointed by and reports to the Facility Director or Compliance Officer and is part of the Research Compliance Program.

RCO responsibilities as defined in Directive 1058.01 5.i. include:

- Auditing facility research projects including performing annual informed consent and triennial regulatory audits of approved study protocols and other post-approval monitoring activities as specified by VA Office of Research Oversight (ORO)
- Informing the facility Director and applicable research review committees about research compliance concerns
- Performing additional research oversight duties assigned by his or her supervisor, including assisting in compliance education to investigators, research staff and research committee staff/members; accreditation activities; the completion of the facility Director's Certification of Research Oversight; and ad hoc audits of individual studies or programs.

Corrective Action Plan

As ACOS and AO, you need to understand the compliance issue(s) being raised during audits or inspections by regulatory agencies and verify that it really is a compliance issue. There have been instances where an inspector or surveyor thought something was a regulation that was not. Moreover, directives and handbooks are revised on a regular basis. What may have been a discrepancy six months ago may no longer be out of compliance. Once all agree that there is a compliance issue, the ACOS and AO are part of the team that helps come up with the corrective action plan for the facility. Wherever possible, correct the non-compliance on the spot. If the matter can't be rectified in the moment it is identified, then a corrective action plan will be needed. Depending on the inspecting entity, this plan may need their approval before implementation. The corrective action plan may be simple or complicated; it may take a short amount of time or a long time. The AO needs to track it and ensure that it is accomplished.

Research Misconduct - Transgressions in Research

Research Misconduct is narrowly defined as transgressions in one of the following three categories: falsification, fabrication, or plagiarism. VHA Handbook 1058.02 outlines the definitions and processes for dealing with Research Misconduct. Any other research transgressions are deemed research impropriety.

The Research Integrity Officer (RIO) is appointed by the Medical Center Director. In many Medical Centers, the ACOS is the RIO but individuals even outside of Research Service can serve in that capacity. The RIO, however, should have some background or experience in research.

The RIO should send out a notice to all investigators and staff regarding reporting of allegations of research misconduct. The RIO receives any allegations of research misconduct and can sequester any data or other records in order to make an initial determination of whether there is sufficient evidence to at least on face value, could be construed as research misconduct; this phase is called the Inquiry phase. Generally, a committee is formed that should include at least a member of the university affiliate if the person alleged to have committed research misconduct is a dual appointee. Working with the affiliate Research Integrity Officer is helpful in any phase of the research misconduct process. It should also be determined if inquiry and if needed, investigation into the research misconduct allegation should be led by the VA or the academic affiliate. With the Inquiry Board, usually a court reporter should be present

to take sworn statements from any witness that would be able to contribute to the Inquiry. Procurement of court reporter services can best be obtained through Human Resources, Labor, and Employee Relations section. Should the Inquiry yield sufficient information to suggest research misconduct, then a formal Investigation is convened with an Investigation Committee. The handling of the Complainant (person making the allegation of research misconduct), the Respondent (person who is alleged to have committed research misconduct), and witnesses, and other evidence is done under the aegis of VA Directive 0700 and VA Handbook 0700. Similar to the Inquiry, the Investigation also involves the recording of testimony by a court reporter.

Summary and recommendations made by the Investigation Committee are reviewed by the Medical Center Director who forwards the report to ORO along with a certificate of completion and concurrence or non-concurrence of the Investigation Committee report. Essentially ORO performs a procedural review to be certain that proper procedures and meeting all timelines were adhered to during the Investigation. If ORO is satisfied that procedural requirements were satisfied, ORO then transmits the Investigation Report, any exhibits and attachments, and the Medical Center Director's certificate of completion to the VISN Director for adjudication. The VISN Director adjudicates the case and renders a decision regarding either clearing the Respondent of the charges, or applying remediation, or other dispositions (these can include government-wide debarment for a defined period; prohibition from conducting VA research for a defined period; removal from a specific research project, or suspension or termination of an active research award; correction or retraction of published article(s); monitoring or supervision of future VA research; required validation of data and/or sources; remedial education and/or mentoring). The VISN Director's adjudication is sent to ORO, and it is ORO that notifies the respondent as to the outcome of the case. An appeal by the Respondent can be done and the appeal is made to the Undersecretary for Health. Final agency decision for a filed appeal is issued from the Under Secretary for Health. In cases where there is no support for the research misconduct allegation, the reputation of the Respondent must be cleared, and it is expected that the Medical Center leadership provide assistance in restoring the Respondent's reputation.

SECTION 14 – Research Management Databases

ePROMISe

ePROMISe ([enterprise] Project Management & Information System) is the database used to inform ORD of all approved research protocols and investigators. It is linked to the VA National Headquarters R&D Computing Center (RDCC) which is responsible for maintaining the VA Research and Development Information System (RDIS) and ePROMISe. You can pull forms from this system that will provide you with information needed to properly enter your studies, such as the funding source codes and administrative codes. Every station has one or more local Administrators who can create local user accounts and reset passwords. If a new Local Administrator account is required, the requestor needs to first obtain local AO approval and communicate with the RDCC via a NSD ticket thru yourIT (icon located on VA desktops). RDCC will create a new Local Administrator account. There are no account request forms for ePROMISe. Please request any NSD tickets being opened to be assigned to the 'ITS ORD SW' group.

RDIS – Accessed thru ePROMISe

RDIS (Research and Development Information System) is also maintained by the Research and Development Computing Center (RDCC). Information from RDIS is sent to the Allocation Resource Center (ARC), to determine the allotment to each facility (through the VISN) of VERA (Veterans Equitable Resource Allocation) dollars. Research VERA is shown in the VERA reports under the ARC website VHA - ARC (va.gov)

More information on ePromise, RDIS and VERA is provided in Section 3.

VAIRRS (VA Innovation and Research Review System)

VAIRRS is the VA's enterprise instance of IRBNet. VAIRRS is the research committee software management platform for all VA medical centers with research programs and is uniquely positioned to withstand the changing pressures of research needs, including:

- oversight needs of the research programs and institutions
- collaborative needs of dually appointed VHA investigators
- regulatory changes of the new Common Rule (2019)

Key benefits of VAIRRS include:

- reduction of administrative load on Research Office staff, committee members, researchers, and their project staff
- improved transparency of research protocol processing
- support for all committee work and allow for institutional tracking of all research and innovation project regardless of funding or regulatory status
- dashboard reporting of key metrics; and harmonized and standardized processes across VA research.

As of 2022, VAIRRS has been rolled out to all active research programs. While there may be programs that continue to use other local committee management systems, all study actions are facilitated by VAIRRS. For additional guidance, email VAIRRS@va.gov or the VAIRRS website.

SECTION 15 – Affiliate University

One of the four statutory missions of the VHA dictates that it conducts an education and training program for health professions students and residents to enhance the quality of care provided to Veteran patients within the VHA. This mission is established under 38 U.S.C. §7301 and §7302, and enacted into policy by the VHA Office of Academic Affiliations (OAA; OAA Policy Documents and Supplementary Materials). Many VA Medical Centers have medical school affiliations with accredited medical schools and osteopathic medical schools for physician education. Additionally, VA medical centers have affiliation agreements with a number of colleges and universities representing numerous other health professions including but not limited to Schools of Dentistry, Pharmacy, and Nursing. OAA reports that in the 2022-2023 academic year more than 120,000 health professions trainees from over 1500 academic institutions received training at a VA facility (OAA Statistics Sheet), under more than 4000 individual program affiliation agreements.

In turn, the VHA Research Program/ORD is codified under 38 U.S.C. §7303, which directs the Secretary of the VA to "carry out a program of medical research [that enables the VA] to carry out more effectively the primary function of the Administration and in order to contribute to the Nation's knowledge about disease and disability." It further directs the Secretary to "act in cooperation with the entities described in section 7302(d) of this title" to accomplish this mission (38 U.S.C. §7303[a][4]). This makes clear that the research mission and education mission of VHA are closely linked to each other, and also inextricably linked with academic affiliate (AA) partners. As noted in a white paper responding to recommendations of the Government Accountability Office (GAO) report on improving relationships between VA Medical Centers (VAMCs), AAs and VA NPCs, the benefits of such partnerships extend across all shared missions, including clinical care, education and research (links to the GAO report and white paper can be found at: VA/Nonprofit Corporation/Affiliate Collaboration Toolkit. Among the successful practices for healthy VAMC/AA/NPC relationships identified in the white paper, first and foremost was "a strong vision and understanding of the overall partnership across many dimensions (patient care, shared faculty, trainees and training programs, research) and an appreciation that individual [partners] may gain in various complementary ways in different dimensions through such a global partnership."

With that broad view always in mind, the remainder of this section is focused on exploring the benefits of the partnership within the research domain, suggested strategies for success, and the key role of the ACOS/AO-R in establishing and maintaining the partnership with the AA. The section on Working with the NPC provides a complementary perspective on that element of the overall partnership.

Benefits of Partnership with the AA:
There are many ways in which the VAMC research program (inclusive of NPC-administered research projects) can benefit from a partnership with the AA, including but not limited to:

1) Joint Recruitment of Investigators: At the heart of any successful VAMC/AA relationship are the dual appointed faculty, and joint recruitment packages for both clinician and non-clinician investigators can often yield a more attractive incentive for recruitment by leveraging what each partner has to offer that may be hard for any single institution in the partnership to match on its own; see also Working with VA NPCs section16 in this manual for contributions the NPC can make to joint recruitment).
2) Dual Appointments for Shared Investigators: NIH and VA have long recognized that clinician and non-clinician investigators in academic medicine careers must work more than a traditional 40-hour work week to be successful in all aspects of their academic endeavors (clinical care, education, research, and local/national service), and have established criteria for MOUs that can codify the distribution of effort and responsibilities across institutions. Most other funding agencies will also accept such MOU agreements for defining total professional effort of their grant awardees.
   NIH has specific requirements that VA and most other funding agencies accept (VA-University Affiliations (nih.gov)). ORD offers some additional guidance (Dual Appointment MOU Guidance (va.gov) on dual

appointment MOUs, including some suggestions for a satisfactory MOU template, as well as important conflict of interest considerations on who can sign for VA on such agreements.

It must be noted that neither NIH nor VA specify a maximum total number of hours/week for such joint professional effort, but the MOU must pass the test of "reasonableness"; in that regard, most VAMC/AA partners with established policy for joint professional effort limit the total hours within a range of 50-65 hour/week, with 60 hour/week being by far the most common.

To avoid potential violations of federal employee conflict of interest criminal statutes (e.g. 18 U.S.C. §§ 208-209) it is important to review and follow the requirements for any needed 208 waivers and Director's approval for Outside Compensation when a VA-paid employee is doing VA research on extramural awards as part of their AA time under the MOU (Outside Compensation Guidelines (va.gov)).

3) Reliance on AA Committees of Record: For programs whose limited resources do not allow them to establish their own standing subcommittees of the R&D Committee (e.g. IRB, IACUC, IBC), or seeking to synchronize review of collaborative protocols between the institutions, ORD policy allows among other options for reliance of the VAMC on the established committees of its own AA, with proper written agreements in place. This requires the AA committees to comply with all VA regulations and regulatory oversight (e.g. ORO inspections, see section 13). For human subjects research, this can facilitate the Single IRB element of the New Common Rule for collaborative protocols, but care must be taken in such cases to clearly delineate the VA and non-VA portions of the protocol.
4) Sharing of Core Services and Equipment: Agreements for sharing of core services and equipment can be unidirectional in cases where one partner has significantly more to offer, but often there are reciprocal opportunities. A successful practice in such cases is to establish an agreement that joint faculty will receive the same recharge rates for core services regardless of what "flavor" of funds they are using (whether AA-, VA- or NPC-administered). VA contracting policies have provisions to facilitate sole source contracts for research-related services. In turn, the AA can engage in sharing of VA services through agreements mediated by the VAMC's Medical Sharing Office in collaboration with Research Service and VA contracting.
5) Sharing of Research Staff: It is possible for dual-appointed faculty to benefit from critical and specialized expertise of staff from a research collaborative partner, and this sharing can be in all directions, whether by dual appointment/ employment (see Outside Compensation Guidelines for important considerations), or some type of staff sharing agreement (e.g. AA and/or NPC to VAMC through IPAs, VAMC to NPC and/or AA through reimbursement agreements, AA to NPC or vice-versa through joint personnel agreements (JPAs)).
6) Joint Applications for Research Funding: At VAMCs with vibrant and robust research partnerships with an AA, combining resources and capabilities across institutions can make for stronger and more competitive applications for funding than what either partner alone could achieve. This synergistic benefit of partnership can exist at multiple levels, starting with partnerships of individual VA and AA investigators on a VA Merit Award or NIH R01; DoD in particular encourages VA partnerships for applications to its various funding programs, and quite often it is optimal for the prime award to be placed through the VA-affiliated NPC, or at least a subaward from AA to the NPC. On a larger scale, many VAMC-AA partnerships include NIH- or ORD-funded Centers that rely upon the collective resources of the partnership; as a concrete example, many NIH Clinical and Translational Science Awards (CTSAs) involve the affiliate VAMC as a critical element of the collaborative consortium.

Successful Practices:

Among the successful practices identified by the VHA Committee that authored the white paper response to the GAO report were the following:

1) Ensuring Understanding of the Overall Academic Partnership: To this point we have highlighted some of the research-specific benefits, and also mentioned the broader range of partnership benefits that extend into the clinical and education domains. To ensure a healthy and mutually beneficial partnership between VAMC, AA, and the NPC, successful sites "focus not only on administration of extramural awards but also include broad consideration of how each partner can contribute in multiple dimensions to research collaboration and resource sharing…research viewed in isolation from the other critical elements of the overall partnership [can

be] associated with strong perceptions of 'competition' for a limited pool of investigator-initiated funding" (VA/Nonprofit Corporation/Affiliate Collaboration Toolkit).

2) Communication Mechanisms: The white paper response to the GAO report emphasized that "Regular and inclusive communication among VAMCS, NPCs, and VA AAs is essential to effective partnerships across the three entities and fosters the inter-organizational collaboration needed to optimize research opportunities." Sites with successful partnerships ensure that research is a regular item for discussion at the OAA policy-mandated Affiliation Partnership Council (VHA Directive 1400.03). Some sites have more regular meetings of VAMC and AA research leadership, ideally incorporating NPC leadership also, to ensure proactive attention to and prompt resolution of emergent issues affecting the dual appointed faculty or the research operations of one or more partners. Specific elements for proactive communication among partners should include but are not limited to:
   - Strategic planning for research program objectives, and where there may be opportunities for synchronization across institutions to maximize the gains.
   - Compliance or research misconduct cases for dual appointed faculty at one site that can impact the partner.
   - Sharing of Critical Research Advancements by Dual-Appointed Investigators, to allow coordination of public announcements/press releases where appropriate.
   - Reciprocal communication on pending grant applications. Regardless of which site administers a prime award, proactive communication at time of submission helps to ensure that any desired resources of the partner can be leveraged in the application without unanticipated barriers to implementation at time of award. This pre-submission communication can also include discussion of the most appropriate entity (AA or NPC) to serve as the prime administrator, and whether a subaward from prime to the other entity is warranted.
   - Educating investigators and departmental grants administrators on policies or agreements in place for where extramural funding is administered (AA vs NPC).
3) Written Agreements: Successful VA and NPC partnerships with the AA also depend on written agreements that can codify the critical dimensions of the partnership, setting expectations and responsibilities for each institution. The need for written agreements includes but also extends beyond those mandated by VHA or other federal policy. Examples of mandated agreements include a Memorandum of Understanding (MOU) when a VAMC seeks to rely upon a research oversight committee of the AA such as the IRB, IBC, or IACUC, as well as the MOUs required by VHA, NIH, and other funding agencies that document combined professional effort of dual appointed faculty.
   Beyond those types of mandated agreements, other types of focused agreements utilized by some VAMC and their NPC include (NRAC-Enhancing-VA-Research-Relationships-White-Paper) Joint Personnel Agreements (JPAs) and IPA agreements for reimbursement of staff effort where appropriate, agreements for reciprocal use of core facilities and services offered by the partner institution, and shared purchase agreements/service contracts, for example whereby an NPC or AA may contribute to ongoing maintenance of VA-owned equipment to which investigators at all institutions have access.
   Perhaps equally important, but less common, are written agreements that formalize critical operational dimensions for dual appointed personnel (DAPs) such as policies and procedures for combined professional efforts, formalized communication in cases of alleged noncompliance/ misconduct, as well as shared oversight and resolution thereof, and mechanisms for administration of extramural awards that include the VAMC as a performance site, whether primary or secondary.
   Sample agreement templates for a variety of needs, vetted by OGC STAR, can be found at VA/Nonprofit Corporation/Affiliate Collaboration Toolkit.
4) Core Faculty Invested in the Partnership: Jointly recruited and appointed investigators who are invested in the shared missions of all partners ensure that an overall understanding of the shared mission extends beyond leadership and throughout the shared faculty. Dual appointed faculty are the backbone of the collaborative clinical, educational, and research missions. While this may not be practical for every clinician or non-clinician investigator within a given university department or VA service, a core of dual appointed faculty within each unit ensures better mutual understanding.

Role of the ACOS/AO-R:

The role of the ACOS and/or AO-R in affiliate relationships includes:

1) to serve as the critical drivers and central liaisons (between affiliate and VAMC leadership, NPC leadership, VA national offices, etc.) in the communication processes that ensure successful partnership;
2) as stewards of all necessary written agreements, ensuring that they remain current, are compliant with all VHA and other federal requirements, and are effective in serving the needs of all partners;
3) participating in joint recruitment efforts in partnership with the affiliate, clinical services, and the NPC;
4) engaging in research strategic planning efforts with affiliate and NPC;
5) establishing efficient and compliant practices for onboarding of affiliate employees as WOCs and IPAs to support the VA research mission, including non-citizen considerations/limitations;
6) advising dual appointees on the intricacies of federal conflict of interest statutes (see section 27), while themselves being mindful of their own roles and potential areas of COI depending on their own university role(s).

SECTION 16 - VA Non-Profit Corporations

Having been established under the Veterans' Benefits and Services Act of 1988 (38 U.S.C. §§ 7361-7366), VA nonprofit corporations (NPCs) have an abbreviated history of partnership with VAMCs relative to academic affiliates, but their contributions to advancing the VHA missions of research and education are considerable. Current authorizing authority for NPCs as codified in 38 U.S.C. §§ 7361-7366, establishes the purpose of the NPCs as providing "a flexible funding mechanism for the conduct of approved research and education at one or more Department [of VA] medical centers and to facilitate functions related to the conduct of research and education and training in conjunction with the applicable Department medical center or centers." The authority permits NPC facilitation of research at a single VAMC, or at more than one VAMC or healthcare center ("multi-medical center research corporation").

Every VAMC with an NPC partner should have an MOU documenting the facility's relationship with the NPC specifically with regard to reimbursements to VA. In addition, it is highly recommended that the VAMC, NPC and academic affiliate have a signed agreement specifying the terms for administration of extramural research conducted at the VAMC by dual-appointed VAMC/affiliate investigators; guidance for such agreements, and decision matrix for determining the most appropriate administrator of the award, can be found at {VA-NPC-Affiliate Toolkit}.

This map displays where and what types of current NPCs support VA Research.

The NPC's Role in Facilitating Research:
While NPCs serve an important role to facilitate both the research and education missions of VAMCs, this manual is for ACOSs and AOs for Research, so we will focus the remainder of our discussion on NPCs role within the research enterprise. To achieve their mission as a flexible funding mechanism in support of VA research, day to day operational management priorities for VA NPCs include purchasing, financial

management, and HR activities pertaining to studies funded by extramural funding agencies, including but not limited to:

- NIH
- DoD
- PCORI (Patient-Centered Outcomes Research Institute)
- Pharmaceutical and Medical Device Companies
- Contract Research Organizations (these are companies hired by pharmaceutical companies to run their multisite studies (e.g., Quintiles, Covance)
- Associations and Societies (e.g., American Cancer Society, Muscular Dystrophy Association)
    - These organizations often provide limited or no overhead (indirect costs), and certain NPCs may have Board Policies that limit their acceptance of grants or contracts with less than the full IDC rate normally charged by the NPC.

Most of the nonprofit's expenses are for salaries, travel, equipment, and supplies related to the funded research proposal. When the funding is from a federal sponsor such as NIH or DoD, or most non-profit associations/societies, the VA is not a formal party to the funding agreement, which is directly between the sponsor and the NPC. However, all research funded through these grants, contracts or awards to the NPC MUST have R&D Committee and all necessary subcommittee approvals (see Section 2) before work can be initiated, as ultimately NPCs do not "conduct research", but rather facilitate the conduct of VA Research. These could be human, animal, or basic science studies.

Research sponsored by for-profit entities such as pharmaceutical companies, contract research organizations on behalf of pharmaceutical companies, or biotechnology companies, also require full R&D Committee and applicable subcommittee approvals, but the VA is more integrally involved in the agreement with the sponsor than is the case for other types of NPC-administered extramural funding. Research done under sponsorship of for-profit entities is generally via a Cooperative Research and Development Agreement (CRADA) with a scope of work required by the company to be accomplished by the VAMC under the direction of the local investigator. Ultimately the CRADA is an agreement between the VAMC and the sponsor on the terms governing the cooperative research, and the Medical Center Director (MCD) serves as the institutional official for VA with binding signature authority on the CRADA, but the NPC is almost always a co-signatory as the administrator of the funds necessary to support the research. Thus, VA and the NPC each have contractual arrangements with the sponsor within a CRADA, but each CRADA must contain a statement that the NPC and VA are independent from one another and that the CRADA does not establish a contract between VA and the NPC.

Because the CRADA is a binding agreement between VA and the sponsor, all CRADAs require review and concurrence by Office of General Counsel, specifically OGC STAR (Specialty Team Advising Research), prior to MCD signature. The CRADA importantly documents rights to intellectual property should any emanate from discoveries made during the research. As is the case for all VA research projects conducted at the facility, the MCD will rely upon the R&D Committee, to advise on appropriateness of the work to be conducted at the VAMC, availability of resources and the funding to support those resources, etc. While the NPC will typically take lead on negotiating the CRADA terms with the sponsor or CRO, and for coordinating with OGC STAR on legal review and concurrence**, the MCD may ultimately want ACOS-R input and concurrence** on the terms of the CRADA and scope of work before signing.

CRADA templates are available on the VA Technology Transfer webpage for Forms, Templates, and Model Agreements. The use of Master CRADAs (CRADA templates that are pre-approved by the pharmaceutical company and the VA) has improved the process flow but not all the pharmaceutical companies have Master CRADAs with the VA.

Prior to negotiating a CRADA, most sponsors will seek to enter into a non-disclosure agreement (NDA)/Confidential Disclosure Agreement (CDA) to protect discussion of proprietary information (the NDA may be two-way if the VA is also expected to provide confidential or proprietary information to inform the feasibility of conducting cooperative research). Although discussions of feasibility of conducting the research at a given VAMC will generally proceed

between the investigator and the company, the investigator is NOT authorized to bind the VA to confidentiality under the agreement. The MCD has the authority to sign NDAs but may **delegate such authority to the ACOS-R** if desired.

Boundaries and Points of Intersection of VA and NPC Operations, and Role of the ACOS-R and AO-R:
NPCs are fully independent 501c3 organizations. Like other nonprofit organizations, they are registered by their state, and are subject to state laws and financial audits. While they are authorized to facilitate research and education projects at their affiliated VA medical center, NPCs are not owned or controlled by the Federal Government, nor are they an agency or instrumentality of the Federal Government.

An NPC's governing body is its Board of Directors. For all nonprofits, including NPCs, the Board of Directors is critical, providing oversight and accountability for the organization. All members of the NPC's Board of Directors have a fiduciary responsibility to the NPC to make decisions that further the interests of the NPC in a manner that is free of conflict of interest. VA statutory members required by VA Policy to serve on the NPC Board are the ACOS-R (more on their role below), ACOS-Education, Chief of Staff, and Medical Center Director. Unlike other Board members, the VA statutory members serve on the NPC Board in their official VA capacities and must ensure that the NPC furthers the best interests of the VA research and education missions.

The NPC must operate administratively separate from VA in its internal business operations, and therefore VA-paid employees, including those in the Research Service, are not to perform activities in direct support of NPC administrative functions except for work that is conducted to establish an NPC, prior to incorporation. However, VA employees DO perform a variety of functions on a regular basis that are a normal part of their VA duties that in turn facilitate the ability of NPCs to support VA research and education. Here are a few prominent examples of the many ways in which Research Service Staff will serve as liaisons between NPC and other VA services to enable the NPC support of VA research:

- Providing information and supporting the processing of staff hired by the NPC to work on VA-approved research projects (note that NPC administrative staff with no direct role in research projects are considered affiliates for badging/computer account purposes, but are NOT to be placed on a WOC appointment),
- Providing information and supporting the processing through VA channels the IPA agreements needed when a project funded by VA intramural dollars is reimbursing the NPC for time of NPC employees on the VA-funded project,
- processing agreements and invoices for the NPC to reimburse VA for VA staff support or clinical services on projects with funding administered by the NPC,
- processing for the VA of necessary agreements between the VA and NPC for ongoing operations (e.g. MOUs for reliance on VA committees of record),
- supporting committee review and approval of projects with NPC-administered funding, and
- coordinating as needed on bringing NPC-purchased IT equipment or laboratory equipment into government use, including processing through Logistics as required for tracking purposes. See VA Handbook 7002 *Part 11 §3.a.*

The ACOS-R and AO-R will therefore work closely with the NPC leadership and support staff to optimally leverage the contributions of the NPC to the overall VA research mission.

As a required (statutory) member of the NPC's Board of Directors, the ACOS-R plays an important role in NPC governance. As part of this combined responsibility of the ACOS-R to serve the best interests of the NPC and VA research mission, it is critical that the ACOS-R involves the NPC, whenever possible, in discussions with the academic affiliate for research partnership/collaborations. In 2023 an ORD workgroup responding to the Government Accountability Office (GAO) report on improving VAMC/NPC/affiliate relationships cited well-established communication mechanisms as a key successful practice at sites with robust three-way partnerships (VA-NPC-Affiliate Toolkit). It was emphasized that the ACOS-R must serve as the key liaison to bridge the affiliate and NPC in such discussions. In addition, successful sites were found to use written agreements to codify important aspects of the partnership in such as reciprocal access to core services of the partner[s], resource/equipment/space sharing,

policies for management of joint appointees, joint recruitment of investigators, shared oversight of noncompliance and misconduct allegations, administration of extramural awards for research conducted at the VAMC, and more (for additional details on VA-NPC-Affiliate partnerships, see Section 15 on Working with the Affiliate, and VA-NPC-Affiliate Toolkit).

At the national level, the VA has responsibility for ongoing oversight of NPCs, and VHA Handbook 1200.17 is a critical document in this regard. It establishes a role for two primary oversight entities for NPCs:

- The **Nonprofit Program Oversight Board (NPOB)** serves as VA's senior management oversight body for NPCs and is responsible for reviewing NPC activities for consistency with VA policy and interests and making recommendations to VHA and VA leadership regarding VA policy pertaining to NPCs.
- The **Nonprofit Program Office (NPPO)** within ORD operates as a liaison between VHA and NPCs, providing oversight, guidance and education to ensure compliance with VHA Handbook 1200.17. This includes performing periodic audits/reviews of the NPCs and issuing requirements for correction of any noted deficiencies. The NPPO will communicate audit results and need for remediation plans through the Medical Center Director, but it is the ACOS-R and AO-R who would typically coordinate with NPC leadership to ensure appropriate corrective actions are implemented. Such corrections may require revisions to NPC business practices and/or Board governance, VA practices with respect to processing of actions that involve NPC projects, or both.

Benefits of the VA-NPC Partnership:

There are many ways in which the NPC can enhance the execution of the research mission at the local VAMC. Some concrete examples are provided here, but it is important to recognize that not every NPC is positioned to offer all these incentives equally; rather, they serve as examples of successful practices that can be reviewed with your NPC leadership and Board for feasibility of implementation, if not already established.

- Greater Relative Contributions to Research VERA than Affiliate-Administered Extramural Funding: As discussed in more detail elsewhere (see Section 3), NPC-administered funds contribute 100% to the Research VERA calculation, just like VA intramural funds. This is in contrast to affiliate-administered funding for research performed at VA, which is discounted to 75% (for peer-reviewed funding) or 25% (for non-peer-reviewed) in terms of its value in the Research VERA calculation. Consider for example the FY2024 Research VERA appropriation {link to ARC-VERA site}, which is based on research expenditures reported on the FY2022 RDIS report:
  - affiliate-administered funding totaled about $267 million nationally, but only about $185 million (69%) contributed to the Research VERA calculations due to the discount formulas applied;
  - NPC-administered funding contributed 100% of the nationwide total of $247 million to the VERA calculation.

  Therefore, NPC-administered funding is a significant contributor to Research VERA funding that provides critical VA research infrastructure support as described elsewhere ((see Section 3).
- Purchase Flexibility**:** As a non-federal partner to the local VAMC, the NPC has flexibility in purchase of equipment, maintenance contracts, supplies, and even IT equipment critical to support the research program of its investigators:
  - in situations where equipment or purchases can support multiple activities funded through multiple sources;
  - in situations where maintenance contracts for equipment critical for VA research are needed; the NPC can obtain maintenance contracts for equipment owned by the NPC, the VA, and in some cases even the affiliate, where the need to support VA research is clear and NPC-administered projects require the use of the equipment, whereas VA funds can only support maintenance contracts for VA-owned equipment;
  - purchase of IT equipment and software needed for VA research that is not routinely purchased by VA OIT (see also section 11 on IT resources); there should be a process in place at the facility where Research Service coordinates with the NPC and local IT and ISSOs for compatibility with the VA network if that is required (there are very few facilities that have separate air-gapped networks

managed by the NPC or the affiliate, although this does occur); there is formal guidance published on mechanisms to bring non-government equipment into VA service through a loan or donation process (see section 11/IT, and VA Handbook 7002 Part 11-3.a); to facilitate use of such equipment, recent efforts of ORD with OIT have established a process for implementing research Local-Area-Networks that allow for software that might not otherwise be approved on VA networks, and that needs periodic updates that are downloaded directly from the vendor.

- Support for Shared Research Core Services**:** Some NPCs provide support for research shared services, including purchase of equipment, maintenance contracts, and in some cases staff to operate the core service.
- Shared Staffing Mechanisms**:** Whether providing a portion of NPC-paid staff research effort to a VA intramural project via an IPA agreement, reimbursing the VAMC for VA-paid staff effort in support of a project with NPC-administered funding (or the affiliate through a Joint Personnel Agreement), such flexibilities in shared staffing allow for deployment of the most qualified staff to support a given research project. This flexibility avoids the need for an investigator's staff to shift their employment status between VAMC, affiliate, and NPC depending on current available intramural vs. extramural funding, thereby promoting continuity of benefits for the staff, enhancing retention rates, and providing stability for the investigator's laboratory.
- Support of Research Administrative Functions**:** Critical support for investigators in preparation and submission of extramural grant applications (pre-award) and administration of funding for awarded grants and contracts (post-award), including staffing, is a critical component of NPC infrastructure support, and should be sized in proportion to its funding portfolio. Accordingly, depending on the size of the NPC and its extramural funding portfolio, the NPC can retain staff in administrative support services like those shown for the VAMC Research Service (see Section XX on Field Research Programs), including grants administration, human resources, and accounting. In addition, the VA Research Program must expend considerable effort as noted above to support research projects with NPC-administered funding, and NPCs can help provide staffing support to the Research Service in proportion to the needs of its funded portfolio (e.g. where NPCs charge fees for IRB and/or other Committee reviews of protocols in CRADAs and other contracts, those fees should help directly offset the expenses of protocol review; this may be accomplished by reimbursing VA for committee analyst effort.

- Contributions to Joint Recruitment of New Investigators: Surveys of the ACOS-R and NPC Executive Director community on Joint Recruitment Strategies identified that the vast majority of VAMCs (80%+) participated in joint recruitment of new investigators/faculty with the academic affiliate, with somewhat less than half of NPC respondents (42%) reporting that they also participated. The survey revealed important unique contributions that each partner was most likely to be able to bring to the table in a joint recruitment package, with space and VA clinical FTE as the most prominent VA contributions. NPCs who participated in joint recruitment with their VAMC and academic affiliate partners reported start-up funds, relocation costs, equipment, and administrative support as common contributions they could make to a recruitment package (Archived NAVREF/ ACOS presentation for details).
- Investigator Support Programs**:** One mechanism of support for new investigators, or established investigators starting new lines of research, that some NPCs offer is flexibility to accept funding from sponsors such as private foundations that have limits on indirect costs (or may provide no indirect costs at all). VA NPCs often have lower indirect cost rates than the academic affiliate, and in some cases may agree to administer these types of awards with limited indirect cost rates. Where it occurs, this is seen as an investment in the future of beginning VA investigators that should prove highly beneficial both for the VA Research Program and the NPC, as investigators supported in career startup by the NPC in such fashion are likely to generate future extramural funding through the NPC at full indirect cost rates, helping the VA research and NPC portfolio to grow together.
  An additional flexibility that some NPCs have is the ability to retain unspent residual funds after completion of studies that are fully closed with the NPC and for which the sponsor does not require that unspent funds be returned. These funds may be used in ways that VA intramural funding often cannot, for example:

- seed/start-up funding for newly recruited investigators, especially if they are bringing existing extramural funding to the NPC.
- pilot funding to allow generation of necessary preliminary data for new extramural grant applications through the NPC, or bridge funding program for established investigators needing general support for continuity of coverage for their laboratories while applying for renewed funding.
- funds for research-related costs such as publication costs or conference attendance without burden to the investigator's intramural or extramural direct research cost funding.

National Association of Veterans' Research and Education Foundations

Soon after the establishment of the first NPCs, in 1992 the National Association of Veterans' Research and Education Foundations (NAVREF) was incorporated as a nonprofit membership organization. NAVREF is dedicated specifically to serving the interests of VA NPCs by "Promoting Partnerships to Improve Veterans' Health." NAVREF regularly convenes NPC leadership and staff to provide training and educational resources on emerging issues related to VA research. Many resources and trainings can also be accessed by NPC Board Members. For more information on NAVREF, go to www.NAVREF.org.

SECTION 17 – Local Facility Support

In some VA locations research is very up front and present at the VA facility (often due to a strong research-oriented university affiliation) but for smaller to medium sized research programs, research may be overlooked, or even ignored in favor of patient care. You may have to figure out ways to bring research to the forefront of the local facility leadership. You may find that there are many misconceptions about research that go back a long way. Some things you may hear (or, *I* have heard):

- Research is not about patient care
- Research is illegal
- Research is making our Veterans into guinea pigs
- Nurses shouldn't help with research studies
- Research is "special." Doesn't have to play by the same rules.
- Researchers don't work as hard as we do; they're never here.

Bottom line: Research can be mysterious at best at some locations and disdained at worst at others.

It's a good idea to participate in facility committee activities. A representative from research on the facility space committee, the Environment of Care Committee, or even the Radiations Safety Committee (research should already be on this latter committee) is a good idea; this helps keep research informed about who is doing what at the local facility and can help research maintain or even expand its space needs. Frequent and positive interactions with facility services help develop support for research. Look for opportunities to help and inform. The ACOS is usually a member of the Medical Executive Committee or other equivalent composed of clinical Service Chiefs and chaired by the Chief of Staff, as well as the Affiliate Partnership Council where these same VA Services are joined by affiliate university leaders and dept chairs to discuss shared education, research, and clinical missions and joint faculty issues (this Council is mandated by OAA policy to meet at least annually for all sites with an academic affiliation). In these venues the ACOS can inform VAMC and affiliate leadership of events, accomplishments, and situations in Research needing the attention of this group and participate in key governance issues.

Who's at Your Facility

- **Medical Center Director (MCD)** – The facility director is the CEO of the Medical Center. They serve as the **Institutional Official** for research.
- **Deputy or Associate Director –** Oversees all of the day-to-day operational, financial, employment, HR, and physical plant issues, and industrial hygiene that support patient care services.
- **Chief of Staff** (COS) – Oversees the clinical policies, daily service issues that directly impact patient care: safety, census, emergencies and crisis management, appointment, and credentialing of all clinicians. The ACOS generally reports directly to the COS.
- **Chief, Nursing Service, Nurse Executive, or Associate Director for Patient Care Services** – Oversees hospital operations as it pertains to nursing staff/patient care and care management.
- **Research Compliance Officer** (RCO) – The RCO reports to the Facility Director or Compliance Officer and audits study regulatory materials for compliance, as well as research office components for compliance.
- **Associate Chief of Staff Education** (ACOS/E) – Manages educational and training mission for health professions trainees of all disciplines and manages the academic affiliation.
- **Committee Manager** – Manages committee activity, including agendas, minutes, rosters, filing of protocol documentation, training of committee members, and follow-up tasks.
- **Budget Analyst** – A budget analyst manages money sent from ORD for research and

administrative use, ensuring that it is properly spent, and that none is left when the funding expires.

- **Procurement Technician** – Orders supplies for research and research administration.
- **Information System Security Officer** (ISSO) – Oversees data security at the VA facility, tells you how to protect information.
- **Privacy Officer** (PO) – Manages privacy of information and advises you what information needs to be protected, and at some facilities is responsible for managing FOIA requests.
- **Radiation Safety Officer** – Liaison between Research Service and the Medical Center's Radiation Safety Program and the Radiation Safety Committee regarding all aspects of use of radioisotopes and radiation producing machines in research.

Depending on the size of the research program there may be several other research administration members, such as a Deputy ACOS for Research, Human Research Program Protection Administrator, a Research Biosafety Officer, an Animal Program Officer, a Grants Administrator, and various Research Committee managers.

Services You'll Interact With:

- Fiscal
  - Even though research money is not doled out through the network (like facility money), fiscal is notified of funds received and responsible for transferring it into the fund control points determined by the research service.
  - You or your budget analyst needs to have frequent contact with someone in fiscal responsible for managing research funds. They will be your resource for obligating 1358s and 2237s, conducting ceiling moves and cost transfers, making necessary adjustments to balance, etc.
  - Do you make patient payments on VA studies? You will need to work with Fiscal on the appropriate reimbursement methods.
- HR (see Section 4 for details)
  - Distinguish if your hire will be through HRMACs for Research funded positions or VISN for medical care funded positions
  - All hiring must go through HR
    - Position descriptions
    - Classification
    - Posting positions
    - Hiring
  - IPAs and WOCs
  - Employee Relations
  - Performance Awards
- Engineering

  There is a constant need to have things fixed, adjusted, or assessed:
  - Air conditioning or heating
  - Leaks
  - Power issues
  - Broken sprinkler heads, ceiling tiles, door handles, etc.
- IT (see section 11 for details)

  Someone's computer isn't working or needs to be replaced. Printers break daily.

- Safety Office (see Section 18 for additional details on Research Safety and Security)

  With all the bio-hazardous materials used in research, your facility Safety Office should work closely with Research Service; VHA Directive 1200.08 Part 6, b. on Membership requires that there be representation of the facility Safety Committee on the SRSS, such as the Safety Officer, Chemical

Hygiene Officer, or member of the Infection Control Committee; in addition, the Radiation Safety Officer should be an SRSS member. If you have an animal and/or bench research program, the Research Service will need to interact regularly with the facility Chemical Hygiene Officer, GEMS manager for hazardous wastes, and the Radiation Safety Officer if radio-isotopes or radiation-producing equipment is utilized in research.

- Logistics (Supply Chain Management; see Section 7 for additional details).
  As described earlier, equipment inventories are an important mechanism for assigning custodial responsibility for research-appropriated equipment, whether shared core resource equipment, or unique equipment used by individual laboratories, and requires extensive interaction with Logistics Service.

- Environmental Management Service (EMS - Housekeeping)
  EMS is an important function to keeping the facilities clean. Hopefully you don't need to have much contact with housekeeping, but you might if you have a housekeeper that is uncomfortable with or not knowledgeable about research.
  You may have staff that need to be relocated. This may involve much assistance from the housekeeping service.

- Police Service – Provide security and conducts security vulnerability assessments.
- Education – provides training support for TMS and manages health professional trainees as well as managing the affiliations.

- Executive
  Since the Facility Director is the responsible and signatory official on many research documents, you will often interact with the Executive office to get these documents completed.
    - Your Director and/or Chief of Staff will be ex officio members of your R & D committee.
    - The Associate Director (for Operations) may be involved helping you deal with Engineering, Fiscal or Housekeeping services.
    - Members of the Executive service will participate in inspection or survey entrance and exit briefings.

Working with Clinical Services

There are occasions when a research project requires the assistance of clinical services support. Most commonly, such clinical services are Imaging (Radiology and Nuclear Medicine), Pharmacy, Nursing, Pathology, and Laboratory Medicine. However, other clinical services at times may also be asked to assist with a research project (e.g. cardiology for catheterization laboratory, EKG, echocardiogram [ECHO]). Assistance with a research project may take the form of additional laboratory or imaging tests that are more than standard of care, or the use of a clinical service employee's time to be involved in a research study. Laboratory and/or imaging tests that are generally requested more frequently than standard of care (blood tests, X-rays, CT, or PET scans, etc.), or a special procedure, such as additional non-invasive testing (ECHO and EKG) or invasive procedures, including endoscopies, vascular catheterizations, and nerve conduction studies (again more than standard of care), incur costs and these costs must be reimbursed to the Medical Care appropriation.

An initial discussion with the Service Chief, or designee of the clinical service from which Medical Center support is needed, should first occur to see if the Clinical Service can support that request. Acknowledgement by the Clinical Service that a research project can be supported should be documented by an Institutional Support signature or memo from the Clinical Service to the Principal Investigator, denoting the specific extent of support to be provided. Remember that VA-funded studies should also have the support of Clinical Services, if required. Requests for a Clinical Informatics service of the Medical Center to assist a Principal Investigator to extract local data should also be approved by

Clinical Informatics if sufficient manpower is available to provide such data search and extraction.

Most Clinical Service Chiefs, who are academically inclined, welcome the opportunity to assist a Principal Investigator, as this also facilitates collaboration with other Investigators. A Clinical Service Chief will also be more inclined to support the research initiative if the facility ensures that the reimbursements for clinical services that were provided are directly available to that Service for coverage of the clinical effort or services provided.

When the Medical Care appropriation is used to assist a research project, reimbursement must occur for services rendered that are over and above routine clinical care and purely for research purposes (38 CFR § 17.102). Reimbursements to Medical Care appropriation for clinical services or "reimbursables," can be accomplished by several mechanisms. After approval by the Clinical Service Chief is obtained, charges for services rendered must be determined. Costs for services can be obtained from VA Decision Support system, prevailing Medical Care Collections Fund (MCCF) rates, "Reasonable Charges" Chargemaster (a national computerized listing of hospital charges for services and supplies, adjusted for local costs), locally adjusted Medicare Rates, Champus/VA Maximum Allowable Charges (CMAC), or even Local Clinical Diagnostic Laboratory Fee Schedule. Once determined how charges are to be set, the charges should carry over for the duration of the study, as grants or contracts will have set fees that – for the most part – cannot be changed over the length of the grant or contract. Current Procedural Terminology (CPT) codes can be used to identify the type of service or test rendered. Once the cost basis methodology is chosen, it may be worthwhile to develop a tracking system by the Principal Investigator, Research Study, enrolled patient, and costs incurred per enrolled patient, if granular detail of reimbursable is desired. An alternative system would be to calculate the reimbursable percentage of the total subject cost (reimbursable costs/total per subject payment). Here, a total reimbursable percentage is determined and for subjects who may not complete a trial, and incur only a fraction of the total reimbursable, charges reimbursed per patient could be higher than actual.

There are also different paths to bill for charges incurred. The Medical Center Financial Management Office, which has a stake in assuring reimbursement of Medical Care appropriation, could provide the Bill of Collection. Alternatively, Research Service Budget Office may be the biller for reimbursables. The organizations that can be billed would be those agencies administering non-VA grants and contracts that used VA clinical services in support of the research grant or contract. These organizations are typically the VA non-profits or the university affiliate. Receivables go to the Agent Cashier at the VA. Funds will be received by the Medical Center as a TDA and will be brought into the 0160R1 reimbursable fund control point. The costs that were incurred by the Clinical Service providing the services, will then be transferred to the 0160R1 FCP allowing for the service line to be reimbursed for the costs incurred. A Standard Operating Procedure and Memorandum of Understanding between the VA and Non-Profit Corporation and/or university affiliate on how reimbursables will occur should be considered. NAVREF has published a guide on Reimbursement of the Medical Care Appropriation (*see Resources for NPC Managers at the NAVREF site*). In addition, the NPPO has issued a Pharmacy Toolkit and Example Bill of Collection process at Document Finder (va.gov)

VA employees whose main duties are in the clinical realm may sometimes be requested to be involved to support a research project (e.g., nuclear medicine technician). A part-time VA paid employee can perform the research duties outside of their established duty hours by a temporary agreement to increase their hours with appropriate reimbursement, or be hired part-time by the NPC or affiliate under the process for facility Director approval of Outside Compensation (Outside Compensation Guidelines: Guidance under development (va.gov)), with clear delineation between their VA tour of duty and the VA non- profit or affiliate tour of duty and scope of responsibilities. A full- time VA-paid employee could be paid overtime for time spent on assisting with the research protocol, if the employee's time assisting a research project is outside of the employee's tour of duty. In cases where an employee is not able to work overtime, or hired in a position that is not overtime eligible (e.g. Title 38), the Clinical Service would need to determine whether a portion of their regular VA-paid tour can be

mapped to research effort to support the project without impacting the delivery of care (note: A local policy that specifies how Research VERA can be used to support clinical backfill for employees providing support to research studies, in a co-investigator or other non-PI support role, is suggested).

Research animal work can be performed in clinical settings on equipment that is required by the protocol. Approval from the Clinical Service Chief is required. Generally, such use of clinical equipment in a research animal setting is done after regular hours or on weekends/holidays. The Animal Component of Research Protocol (ACORP) covers use of animal research in clinical care environments.

SECTION 18 – Research Safety & Security

Directives & Handbooks

The following directives and handbooks address research safety and security and can be found at VA Publications:

- VHA Directive 1200.08 – Safety of Personnel Security in Laboratories involved in VA Research
- VHA Directive 1058.01 - Research Compliance Reporting Requirements
- VA Directive 7700 – Occupational Safety and Health
- VA Handbook 7700.1 – Occupational Safety and Health Handbook
- VHA Directive 7701 – Occupational Safety and Health Program
- VHA Handbook 7701.1 – Occupational Safety and Health Program Procedures
- VA Handbook 6500 – Information Security Program
- VA Handbook 1200.12 – Use of Data and Data Repositories in VHA Research

SRSS (Subcommittee on Research Safety & Security)

The Research and Development Committee has a subcommittee to assess the safety requirements of each research study (human, animal, and basic), usually referred to as the Subcommittee for Research Safety (SRS). This committee must ensure that research is conducted safely in terms of the use of chemicals, biological agents, reagents, procedures, exposure, protection, storage, and training. This committee is not responsible for assessing the scientific merit or fundability of a protocol, although it may make recommendations to the appropriate committee pertaining any of these concerns.

It is optimal if all subcommittees of the Research and Development committee (R&DC) can easily and freely communicate with each other, as well as with the R&DC.

As AO, you will be an *ex officio*, non-voting member of the SRS. It is your role to ensure that the Safety Committee has all the information it needs to make informed decisions and is performing its duties, as described in your facility's SOPs.

Institutional Biosafety Committee

If your research program is engaged in research involving recombinant DNA then you will need to have committee oversight from an Institutional Biosafety Committee (IBC) which is registered with the Office of Biotechnology Affairs (OBA) at the NIH.

Some facilities have their safety committee function as the IBC. The IBC will need to have and follow an SOP for how to function and document its activities. You may use the affiliate's IBC if your MOU with the affiliate university allows for it.

The research program will need to name a Biological Safety Officer (BSO), who will be a member of the IBC. The BSO will also be responsible for performing periodic inspections of areas involving rDNA research to ensure that lab standards are rigorously followed.

Who Must Be On the IBC

- No fewer than five members, so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research, and to identify any potential risk to public health or the environment.
- At least two members shall not be affiliated with the institution (apart from their membership on the IBC), and shall represent the interest of the surrounding community, with respect to health and protection of the environment.
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experimentation use is planned (probably not applicable in the VA setting).

- The IBC shall include at least one scientist with expertise in animal containment principles when experiments using animals are done.
- When the institution conducts recombinant DNA research at BL3, BL4, or Large Scale (greater than 10 liters), a BSO is mandatory, and shall be a member of the IBC.
- When the institution participates in or sponsors recombinant DNA research involving human participants, the institution must ensure that the IBC has adequate expertise and training (using *ad hoc* consultants as deemed necessary).
- A member representing the laboratory technical staff.

The Institution shall file an annual report with NIH/OBA, which includes:

1. A roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable), and
2. Biographical sketches of all IBC members (including community members).
3. If utilizing the affiliate IBC, you must include your MOU.

Safety Compliance (see also Section 10 for details on Emergency Preparedness)

According to the VA Directives and Handbooks, there are several required safety inspections. These can be combined with other facility inspections, if members of your safety committee belong to facility inspection groups, e.g., environmental rounds.

ORO frequently publishes checklists on their website that can be used to help you ensure that the research service is covering all the bases for safety and security.

Security

Each research program needs to address the requirements as it pertains to security. This can mean physical and personnel security, as well as data security (see Section 21 Privacy and Data Security for details).

Each year a multidisciplinary team (members include HR, Police, Safety, and Research) must review the research facilities and program for research security. If a subcommittee is formed for this purpose it would report to the R&DC through the SRSS committee, or it might be a direct report to R&DC. Research Security can also be addressed as a work group or task force and therefore would not require a separate SOP and program review.

Police Service

Your facility has a Police Service that is the central monitoring group for security access systems at your facility, including research areas. As AO, you should work closely with your Police Service to routinely review access records to research areas.

Anytime there is an incident of theft or vandalism, etc., make sure it is reported to the Police Service by the people involved or knowledgeable of the incident.

If you need access to the facility over the weekend, you may need to be given access by the police service. As AO, you should not need any further approval for this but if your staff will be coming in on the weekend, you may need to notify the Police Service and give them your approval.

SECTION 19 – Animal Program

The Directive that covers the animal program within the VHA is:

- VHA Directive 1200.07 - Use of Animals in Research which was reissued on March 23, 2023.

Much information can be found at VA Animal Research Program including guidance and training
The other document that is heavily used to ensure that animal research is performed ethically is *Guide for the Care and Use of Laboratory Animals* (NRC 2011). The 8th edition (© 2011) can be found at Regulations & Standards | OACU (nih.gov)

Veterinary Medical Unit

The area of the medical center where the animals are kept is called the Veterinary Medical Unit (VMU). This area is led by the veterinarian for the research program or Veterinary Medical Officer (VMO). The VMO can either be a VA employee or a contractor and must be a licensed veterinarian.

The VMO directs the operations of the VMU, oversees the animal care staff and ensures compliance with animal welfare laws, regulations and policies concerning VA animal research.

VMU staff are responsible for feeding, caring for, and maintaining a clean environment for the animals. They keep a daily census of animals and notify researchers when there are changes in the condition of their animals. They monitor the temperature in the animal rooms. They may be engaged in quarantine activities as well as the disposal of animal carcasses. They handle the intake of new animals into the VMU. Sometimes VMU staff assist researchers with their research activities, but this varies by facility and is not considered part of their normal duties.

Institutional Animal Care and Use Committee

The animal program is governed by an animal committee, usually referred to as the Institutional Animal Care and Use Committee (IACUC), which is another subcommittee of the R&DC. This could be a local VA IACUC or the IACUC of the academic affiliate.

The IACUC reviews animal protocols and ensures compliance with regulations governing the use of animals in research studies. Senior research staff, including the AO, may serve on the IACUC as non-voting members.

The AO should help the IACUC make informed decisions by being knowledgeable of the animal program SOPs. Refer to your local SOP and/or Section 8 in *Handbook 1200.07* for detailed information. The RCO may be an invited guest of the IACUC; this can be a permanent invitation if included, as such, in the IACUC SOP.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care)

AAALAC International is a private, non-profit, internationally accepted organization that accredits institutions that meet its standards of humane treatment of animals in science. These standards go beyond minimum legal requirements to promote excellence in animal care and use. Participation in AAALAC's accreditation program is voluntary, but VA policy requires all VA animal research programs to earn and maintain full accreditation.

Assurance

Your research program's animal assurance (the counterpart to the human research Federal-wide

assurance) is managed through the Office of Laboratory Animal Welfare (OLAW) which is a branch within the National Institutes of Health (NIH).

Reports

Every year the Research program needs to provide information to different entities about its animal research activities.

- USDA Annual Report – Due on November 15
- AAALAC
  - Annual reports
  - Triennial Program Description
- ORD Annual Station Data Report – due January 15
- OLAW Annual Report – due on December 1

SECTION 20 – Human Research Protection Program

The Human Research Protection Program (HRPP) encompasses the IRB and all matters pertaining to research involving human subjects at the VA facility.

The HRPP is comprised of facility senior management, members of the research office, the IRB, the R&DC, and all the members of the research team conducting human studies. Together, this group is responsible for protecting the rights, safety, and well-being of subjects enrolled in research projects.

The definition of HRPP found in *VHA Directive 1200.05* is: "A comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the VA facility Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the R&D Administrative Officer, the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), compliance officers, information security officers, privacy officers, and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research."

Your research program will have at least one Standard Operating Procedure (SOP) dealing with the HRPP – or maybe several. It is regulated by *VHA Directive 1200.05*.

Enterprise Protections, Regulatory, Outreach, and Systems

At ORD, there is an office called ePROS (Enterprise Protections, Regulatory, Outreach and Systems) that provides resources to support the implementation and management of the human research protection program. Their website is located here: ePROS - Enterprise Protections, Regulatory, Outreach, and Systems (va.gov) .
ePROS is responsible for 1) developing policy and guidance on VA human research protection; 2) training and education for human research protection; 3) ensuring that all VA facilities that conduct human research achieve and maintain full accreditation of their HRPPs; and 4) creating and implementing the VA Central IRB. (NOTE: ORO, not ePROS, is responsible for FWAs.)

FWA or Federal-Wide Assurance

Because your HRPP is part of a federal organization it must have a Federal-Wide Assurance (FWA). The HRPP operates under this FWA. Each FWA must be renewed every 5 years or within 30 days when there is a change in the facilities Institutional Official, who is the signatory official on the assurance. Each time the FWA is updated, a VA Addendum must also be submitted through the VHA Office of Research Oversight (ORO) to OHRP. (*Note: there is OHRP assurance training that must be completed by the signatory officials.*) Federalwide Assurance (FWA) Registration Instructions - Office of Research Oversight (va.gov)

Belmont Report

This report was issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on September 30, 1978, and was later published in the *Federal Register* on April 18, 1979. It took its name from the Belmont Conference Center, located in Elkridge, MD, where the document was drafted in part. The three fundamental ethical principles are:

1. Respect for persons: Protecting the autonomy of all people and treating them with courtesy

and respect and allowing for informed consent. Research must be truthful and conduct no deception;
2. Beneficence: The philosophy of "Do No Harm" while maximizing benefits for the research project and minimizing risks to the research subject; and
3. Justice: Ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly – the fair distribution of costs and benefits to potential research participants – and equally.

As part of your FWA, your institutional official will attest that your HRPP follows the principles of the *Belmont Report*.

The Common Rule

Seventeen federal agencies (including the VA) joined Health and Human Services (HHS) in adopting a set of rules for the protection of human subjects known as "the Common Rule." These requirements are set forth in Subpart A of 45 Code of Federal Regulations (CFR) Part 46 for the Department of Health and Human Services (HHS). VA adopted the Common Rule as 38 CFR Part 16 which is identical to 45 CFR Part 46. Subparts B, C, and D were added to provide additional protections for pregnant women, human fetuses, and neonates (B), prisoners (C), and children (D). VA has not formally adopted Subparts B, C, and D, but some of their provisions are included in *VHA Directive 1200.05*.

On January 19, 2017, a major revision to the Federal Policy for the Protection of Human Subjects was published and subsequently revised January 22, 2018, and again June 19, 2018, that requires compliance of studies approved by the IRB or determined to be exempt by IRB on or after January 21, 2019. The revised Common Rule allows for continued compliance with the pre-2018 Common Rule for those studies approved by the IRB or determined to be exempt prior to January 21, 2019. Studies originally subject to the pre-2018 Common Rule may transition to the revised Common Rule on or after January 21, 2019. If a study originally subject to the pre-2018 requirements is determined to transition to the revised Common Rule, the IRB will document and date the determination within the minutes or within the electronic protocol file. Studies that transition to the revised Common Rule must comply with all applicable 2018 Common Rule requirements on the documented date.

Working with Boards and Committees

Research and Development Committee
Governed by *VHA Directive 1200.01*, the committee is tasked with oversight of the local research program, broad areas of program development, risk management, and quality and performance activities. Perhaps the most variability exists in how VA R&D Committees function, as they are no longer tasked with individual protocol review. Some R&D Committees have retained this responsibility, and some have not. The ACOS serves as the Executive Secretary of the R&DC and the AO may be an ex officio, non-voting member of this committee and will be depended on to help the committee make informed decisions. The SOP for the R&D Committee must reflect your specific processes that comply with the requirements of VHA Directive 1200.01. The complexity and intricate review processes for research studies through the R&DC and its subcommittees cannot be overemphasized. It requires expert support, well-organized processes, and explicitly written procedures. *Resources:* https://www.va.gov/ORO/orochecklists.asp

Institutional Review Board (IRB)
A significant component of the HRPP is the Institutional Review Board (IRB). The IRB must review each human subject project, initially, and then at least annually after it has approved the project. The elements of its review are numerous and multifaceted and predominantly guided by the *Code of Federal*

Regulations or the *Common Rule* and *VHA Directive 1200.05* which deals with protection of the human subject and the informed consent process. The IRB is a subcommittee of the R&D Committee.

The ACOS/AO may be *ex officio*, non-voting member of this subcommittee and may serve as consultants regarding research processes. This means understanding program SOPs, in light of the issue being discussed. The ACOS/AO should be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts. One solution is to limit the attendance of the AO/ ACOS to the general business portion of the meeting. This enables the ACOS/AO to remain aware of how the committee is functioning but eliminates the perception that they are influencing the discussion and review of individual protocols. The IRB may meet monthly or more often depending on local need (i.e., the size of the research program; number of protocols). A facility may have more than one IRB, may use the VA Central IRB, the IRB of the academic affiliate, an IRB of another VA facility, an IRB of another federal agency or a commercial IRB that has been vetted and approved by ORD. Requirements for using services of another entity's IRB are outlined *in VHA Directive 1200.05*.

Affiliate IRB

A Memorandum of Understanding (MOU) or Authorization Agreement with other VA facilities or external organization(s) providing IRB services (see VHA Handbook 1058.03 and MOU Checklist: https://www.va.gov/ORO/orochecklists.asp must be established and a written SOP should be in place and must be consistent with *VHA Directive 1200.05* when reviewing VA research. It should also cover how communication will occur between the VA and the affiliate IRB (many times, this is the "weak link" when problems occur in minutes from the affiliate IRB, and other communications regarding the VA protocols that do not get back to the VA). You must also ensure that the external IRBs of Record used by the VA facility hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03.
Establishing the affiliate IRB as the IRB of record also needs CRADO (Chief Research and Development Officer) approval if this is a change in their IRB of Record or establishes a new HRPP.

VA Central IRB

At VHA Central Office in the Office of Research and Development (ORD), there is a VA Central IRB. The VA Central IRB reviews studies with greater than three sites where the study procedures are the same across sites. Therefore, if you have CSP, CSR&D, RR&D, or HSR&D/QuERI or NPC administered multisite studies then you may use the VA Central IRB as one of your designated IRBs. More information can be found at VA Central Institutional Review Board (IRB).

While each VA facility has ultimate responsibility for its HRPP, the VA Central IRB provides expert ethical and scientific review of VA funded multisite projects. The centralized review is meant to enhance the efficiency of IRB review for these projects.

Each VA facility that plans to use the VA Central IRB must add the VA Central IRB to its Federalwide Assurance (FWA) (in coordination with ORO per *VHA Handbook* 1058.03) and should have an MOU between the VAMC, the local NPC, and the VHA Central Office describing the respective roles and responsibilities of VHA Central Office, your local NPC, the local VA facility, and the VA Central IRB. . If one is not in place and your site has been identified as a potential participant in an ORD funded multisite study, contact the VA Central IRB Administrator. Contact information is available through the ePROS and VA Central IRB links on the ORD Website. An MOU template will be provided. (NOTE: The Institutional Official for the VA Central IRB is the Principal Deputy under Secretary for Health.) There is variability among research programs in regard to internal processes that encompass the review of VA Central IRB studies. You should have internal SOPs that cover the review process for studies managed by the VA Central IRB.

VA Central IRB Liaison

There is a local individual designated by the Facility Director who is responsible for reviewing the VA

Central IRB determination and providing comments (e.g., on special local considerations and requirements) before the final VA Central IRB approval. This person can be the local IRB chairperson, ACOS, R&D chairperson, HRPP Administrator, or another qualified individual. All communication with local site research personnel is through the Local Site Liaison who will be copied when approved study documents are released to the Local Site Investigator or when an action is taken by the VA Central IRB (such as, determining that a reported event is not related or not serious). The VA Central IRB has many other communications with the local study teams in which the local site liaison is not involved. Note: Protocol review and relevant communications are now done through VAIRRS. For reportable events that are serious and further reportable, the VA Central IRB will also include other local site research and other personnel on those communications per *VHA Handbook* 1058.01. For additional information, the Central IRB website can be accessed at: www.research.va.gov/vacentralirb

IRB of Another Federal Agency

VHA Directive 1200.05 allows the use of an IRB of another Federal Agency through an Authorizing Agreement. To use the NCI Central IRB, the VA must develop SOPs to describe the roles and responsibilities of the VA and the NCI Central IRB – these must be approved by ORO. Once the SOPs are approved and registration is done through NCI, the VA must sign the Authorizing Agreement with NCI and amend its FWA to add NCI Central IRB as an IRB of record. For more information, refer to the following National Cancer Institute (NCI) IRB Information (va.gov)

Commercial IRB

Only commercial IRBs vetted and approved by ORD, and with which ORD has executed a Master Services Agreement may be used by VA Facilities. Steps for requesting an IRB Arrangement with a Commercial IRB are detailed at IRB Relationships in the VA: Single IRB Exceptions, Independent (Commercial) IRBs, and changing IRB reliance by the VA Facility. It is important to note that there are VA specific requirements for informed consent and HIPAA Authorizations for Commercial IRB submission. A checklist has been developed by ORD to assist VA Facilities with preparing the informed consent documents and combined informed consent/HIPAA authorization. The checklist is available at the link above.

Single IRB Mandate (https://www.research.va.gov/programs/orppe/single_irb.cfm)

January 20, 2020, was the compliance date of the cooperative research provisions in 38 CFR§16.114 of the 2018 Requirements. As of January 20, 2020, all VA Non-Exempt Human Subjects Research approved or transitioned to follow the 2018 Requirements of the Common Rule must use a single IRB unless an exception applies to the research activity if more than one institution is engaged in the research and any of the following applies to the multi-site research:

- The cooperative non-exempt human subjects research is funded or supported by any of the federal agencies or departments who agreed to apply 2018 Requirements.
- Any of the other institutions are federal agencies or departments who agreed to follow the 2018 Requirements, including other VA Facilities

For more information on requesting an exception – go to IRB Relationships in the VA: Single IRB Exceptions, Independent (Commercial) IRBs, and changing IRB reliance by the VA Facility

Subcommittee on Research Safety

Subcommittee on Research Safety (SRS) is covered elsewhere in the manual but should be considered as part of the intricate and multifaceted review process described in this chapter.

Non-Research Committees Responsible for the Review of Research

Pharmacy and Therapeutics Committee

In its review of research, the Pharmacy and Therapeutics (P&T) Committee is guided by the *VHA Handbook* 1108.04. The P&T Committee must review a research protocol when it concerns a study that involves an investigational product, as well as any Cooperative Research Agreement. This review must take place before the ACOS provides final notice of study approval or initiation. It is suggested that there is research program representation on the P&T Committee and/or the study PI attends the meeting in which their study is to be reviewed. It is also recommended that the Research Administration/HRPP Office provide a template for P&T Committee Review that allows for documentation and determination of study review. Depending upon the Research Program Office, it is either up to the Administrative Office, or the study personnel to ensure that study material is submitted for review by this committee within the accepted timeframe.

Radiation Safety Committee

In its review of research, the Radiation Safety Committee is guided by *VHA Directive* 1105 and *VHA Directive* 1129. Per the directive, the Radiation Safety Committee must "review research protocols that require the use of ionizing radiation as part of the research" and/or "involve the medical use of machine sources of ionizing radiation." This review must take place before the ACOS provides the final notice of the study's approval or initiation. It is suggested that there is research program representation on the Radiation Safety Committee and/or the study PI attends the meeting in which their study is to be reviewed. It is also recommended that the Research Administration/HRPP Office provides a template for Radiation Safety Committee Review that allows for documentation and determination of the study review. Depending upon the research program, it is either up to the Administrative Office or the study personnel to ensure that study material is submitted for review by this committee within the accepted timeframe.

Key Issues to Address When Terminating Human Subject Studies at a VA Facility with a Human Research Protection Program

VHA Office of Research and Development, March 25, 2016

Category	Issue	Comment
1. Timeline	Define the date for the projected closure of the Human Research Protection Program (HRPP)	Intervals vary anywhere between 60 days to 1 year, with the usual range being between 3 to 9 months.
2. Notification of any relying HRPPs	Any HRPP relying upon the VA Facility's IRB of Record and/or Research and Development Committee must be informed immediately as this directly impacts the relying VA Facility's HRPP.	
3. Categorization of studies: (a) which studies are non-human subjects, exempt, or non-exempt human subjects (b) funded (ORD, other federal funding, industry) (c) collaborative (d) Repositories – data or biospecimen	Different studies will have different issues involving termination and/or transition.	If there are any studies with CRADAs, the termination clauses of those CRADAs need to be reviewed. For data and biorepositories, every effort should be made to transfer those studies as permitted within the approved protocol and the applicable informed consent and HIPAA authorization.
4. Subject status: Determine which studies have subjects which are currently receiving any study-related interactions, interventions, and/or follow-up monitoring.	Subject safety is the priority for terminating and/or transitioning any human subjects study.	Determinations must be made for any notifications that must be made for subjects in any currently active human subjects studies.
5. Transfer of studies: Determine if any of the studies will or can be transferred to another institution	It is unknown whether any of the studies will or can be transferred to other VA facilities.	

Category	Issue	Comment
6. Notification of Investigators: Include plan for terminating and/or transitioning studies as well as actions they are required to implement, including subject issues, equipment inventory, and records retention for investigator study records.	VA Investigators must be informed quickly of plans to terminate and/or transition any studies so that study-specific issues can be identified.	
7. Records issues: Determine how research records will be made available for any studies which will be transferred, as well as determine how research records will be retained for purposes of VA's Record Control Schedule.		
8. Notification of key parties	Depending upon the study, additional individuals, or entities (Collaborators, FDA, funding agencies) may need to be informed. Those groups will be identified based upon the study.	
Please note that the above is general guidance in brief bullet-format statements and is not intended to address specific issues that may be associated with specific studies. ORD is available to assist as needed on this topic.		

SECTION 21 – Privacy & Information Security

Directives & Handbooks

The following directives and handbooks address research safety and security and can be found at VA Publications:

- VA Directive 1605.01 – Privacy and Release of Information
- VA Directive 1605.02 – Minimum Necessary Standard for Protected Health Information
- VA Directive 1605.03 – Privacy Compliance Assurance Program and Privacy Compliance Monitoring
- VA Handbook 6500 series

A good location for Privacy information is the VA Privacy Hub (VA Privacy Service Privacy Hub - Home (sharepoint.com). You can find general information as well as a listing of privacy officers. As mentioned above in the IT Section, every facility has a Privacy Officer (PO). You should address any questions you have about Privacy to the PO. However, some POs have little or limited experience with the research setting. They might need help with research Privacy issues. Your RCO may be helpful and there is also a Privacy Board within ORD that can help resolve issues and answer questions.

Privacy Officer (PO)

The Privacy Officer (PO) is responsible for ensuring that patient information meets all privacy regulations. This critical position tells us what needs to be protected. This person is responsible for HIPAA documentation. The Privacy Officer needs to review each initial submission of human research studies. Privacy is not a concern in animal studies. The PO will work with the research team to address or correct any privacy issues. A final review must be conducted by the PO prior to R&D Committee approval The PO serves in an advisory capacity on the IRB or R&DC as *ex-officio* non-voting member or consultant. (See VHA Directives 1200.01 and 1200.05 for more information). They also review all human subjects' projects at the time of initial review to ensure that all required privacy protections are in place. He or she must document the review and receive a copy of the approval paperwork once the project receives final approval. You can identify your local Privacy Officer by using the PO Locator.
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The Privacy Officer should be an *ex-officio* non-voting member of either the IRB or the R&D committee.

Information System Security Officer (ISSO)

The ISSO is the person at your facility that is responsible for data security. The ISSO will review all initial submissions of research protocols to ensure that study data is managed, according to VA regulations. The ISSO will resolve any questions or concerns directly with the researcher submitting the study.

As you know from your Privacy and Information Security Training, any breaches of information security are reported by the person involved directly to the ISSO, ACOS and the PO (if it involves people). The ISSO may have to report the matter to the National Security Operations Center (NSOC). The ISSO should notify the ACOS / R&D that an NSOC incident has been entered. This triggers the need for the Director to notify ORO of the incident within 5 business days. See *VA Handbook 1058.01* – Research Compliance Reporting Requirements for more details. https://www.va.gov/ORO/oropubs.asp

The ISSO should be an ex officio non-voting member of either the IRB or the R&D Committees

SECTION 22 – Site Visit Coordination

The research program is often inspected, surveyed, and site visited by internal and external groups. These can be "for cause" (an allegation of non-compliance has been reported or noted) or routine. Some entities that may review the research program are:

- ORO (Research Specific)
- OIG (periodic facility inspections in defined areas, also for-cause)
- GAO (as commissioned by Congress typically)
- FDA
- USDA
- OSHA
- CDC
- ITOC
- AAALAC
- EPA

You will probably have facility groups that want to perform inspections or walk-throughs:

- Annual Workplace Evaluation (AWE)
- Environment of Care Rounds
- Safety
- ISSO
- IT or IRM
- Controlled Substance
- Space

Hardly a week will go by during which you are not coordinating, or participating, in some type of research-specific program review, or facility-wide review including research areas. You may need to help coordinate the submission of documents for the review. These would include minutes, agendas, SOPs, and reports.

You may need to help set the agenda for the inspection and coordinate the people needed to be in attendance.

In some instances, you will be asked to help with hotel reservations, meals/restaurant locations, and transportation for the visiting inspection staff.

Remember, you are not alone!

There are many other people who are responsible for the success and compliance of the research program. As the ACOS and AO, you have an enormous role in this – but depending on the particular inspection, the RCO, Privacy Officer, Safety Officer, Police Service, and R&D Committee and its subcommittees are responsible entities, as well.

SECTION 23 – VA Technology Transfer Program (TTP)

Technology Transfer Program (TTP) facilitates the commercialization of invention to benefit Veterans and the Public. Most often it involves licensing a patent to a company which will develop the invention into a product that benefits the public.

- Inventions made by VA employees (including WOCs, IPAs, etc.) are disclosed to VA TTP as required by law.
- TTP, in conjunction with VA lawyers, makes a determination of rights (DOR) regarding whether the VA asserts any rights to the invention. See Directive 1200.18
- A researcher may have a third-party employer, such as an academic affiliate or other research institution which may also assert rights to the invention. VA TTP works with the affiliate's technology transfer office to develop and commercialize the invention.
- Typically, either the VA or the affiliate takes the lead in, inter alia, assessing the invention, filing a patent, and ultimately licensing the invention.
- Royalties are distributed to the inventor(s), VA labs - with the VAMC where the invention was made receiving the majority lab share - and, if applicable, to institutional joint owners of the invention. When another institution takes the lead for an invention, VA receives a royalty share from the Lead institution, and distributes in accordance with VA policy to the VA inventor(s) and lab(s). See TTP Royalty Distribution Procedure.
- Each VA inventor completes a certified statement providing all information requested by VA TTP regarding the facts and circumstances leading to conception and/or actual reduction to practice of the invention. Each VA inventor's immediate superior reviews the form for accuracy and certifies that their respective employee's statement of circumstances attending the invention is or is not correct, giving reasons if pertinent.

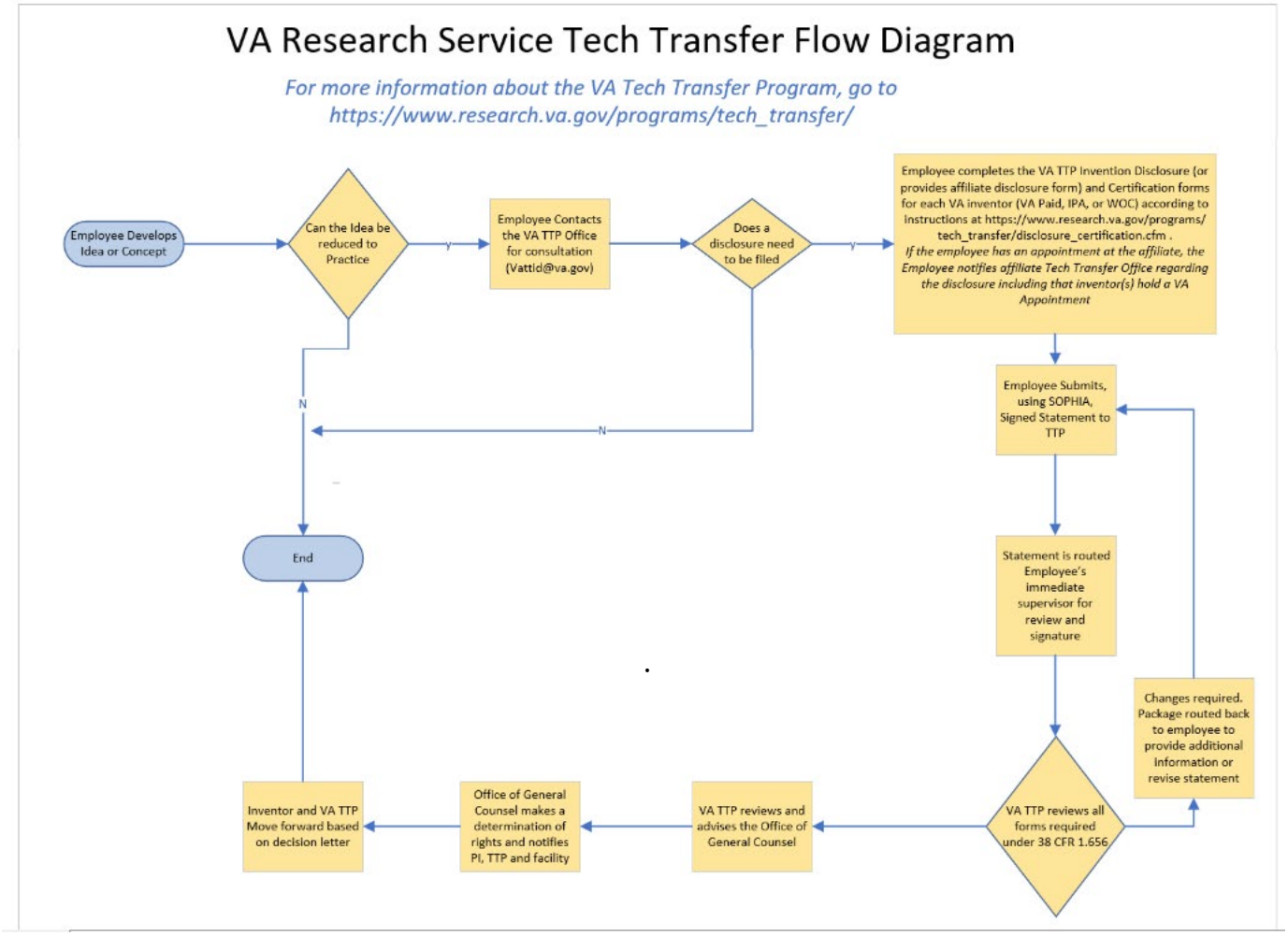
TTP also reviews CRADAs in conjunction with the VA legal team dedicated to research issues (Specialty Team Advising Research (STAR). A CRADA is an agreement between the VA and another party (typically an industry partner) in which the partner typically provides funding, and the VA provides personnel, services, facilities, and other resources. The CRADA defines the responsibilities and obligations of each party as well as their rights to intellectual property. CRADAs are typically executed between the VAMC, the industry partner, and the VA-NPC (who administers the funds). In general, the CRADA will also spell out intellectual property rights of each participating party a priori of any invention being made. See *VHA Directive* 1206: Use of a Cooperative Research and Development Agreement (CRADA)

There are other guidance documents and templates for various other types of Intellectual Property type issues such as Confidential Disclosure Agreements, and Material Transfer Agreements that can be found at the Tech Transfer page at https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm.

Since many of the researchers at the VA also have an appointment at the affiliate university, and are thus dual employees, it is helpful to have the VA and the affiliate enter into an intellectual property administration agreement. The older model is the Cooperative Technology Administration Agreement (CTAA), but these will be transitioned to the newer Invention Management Agreement (IMA). Template for the IMA can be found at the above link. These agreements cover which institution will pursue a patent if warranted, which institution will seek marketing partners, and how royalties would be divided between the institutions. Also, the VA Technology Transfer Program will usually accept the Invention Disclosure Forms from the affiliate but still require the completion of the VA Certification form for each VA inventor defined as a VA-paid employee, a WOC, or an individual on an IPA. The VA Invention Disclosure and VA Certification process can be initiated through the process outlined at:
https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm

1. Employee completes the VA TTP Invention Disclosure (or provides affiliate disclosure form) and Certification forms for each VA inventor (VA Paid, IPA, or WOC), according to the instructions provided at: https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm

2. Employee submits signed statement to TTP, and statement is routed to Employee's immediate superior in VA for review and signature.
3. Forms completed fully and receipt of all information required under 38 CFR § 1.656 confirmed by VA TTP.
4. Package routed back to employee to provide additional information or revise certified statement.



SECTION 24 – Records Control Schedule

The Federal Records Act (FRA) requires that all Federal agencies make and preserve records that pertain to the functions, decisions, and other actions of the agency. As applied to VA research records, the FRA defines Federal records as all documentary material, regardless of physical form, or characteristics made or received by a VA research program or, in accordance with, the transaction of the Agency's business, (i.e., the conduct of VA's research programs and VA research) and that are preserved or are appropriate for preservation as evidence of VA's activities or because of their informational value of data in them.

What are Records?

A record is created during the process of conducting business (e.g., correspondence, agreements, studies, etc.); received for action (e.g., FOIA requests, controlled correspondence, grant applications, etc.); documents VA activities and/or actions (e.g., calendars, meeting minutes, project reports, etc.); mandated by statute or regulation (e.g., administrative records, dockets, etc.); supports financial obligations or legal claims (e.g., contracts, litigation case files, IPAs, etc.).

A non-record is reference material (e.g., vendor catalogs, phone books, technical journals, etc.); a convenience copy (e.g., duplicate copies of correspondence or directives, etc.); stock copy (e.g., VA publications, etc.); draft or working copy (e.g., draft with no substantive comments, rough notes, calculations, etc.). **PLEASE NOTE:** Some drafts are needed to support the decision trail or are required by a records schedule.

Working Files include budget calculations, comments, rough notes, proposals, evaluations, preliminary outlines for a report, lists of suggested topics to be included in a memorandum, informal comments received on draft publications, and documents used to brief staff on a proposed item.

Personal Papers do not relate to, or have any effect upon, the conduct of agency business. Documents created before entering government service, private materials brought into, created, or received in the office that were not created or received in transaction of government business, and/or work-related personal documents that are not used in the transaction of government business. **PLEASE NOTE:** Personal planners and calendars might be records, if they document your activities for the VA.

The Life Cycle of Records

Creation: Records created, received, or collected through the daily transaction of business

Maintenance and Use: Filing, retrieving, use, duplication, printing, dissemination, release, or exchange of the information

Disposition: Assessment to determine the retention value of the record, in accordance with the record's schedule, and leads to either the preservation or destruction of the record

It could be a record if…

- It reflects significant actions taken during the process of conducting business.
- It contains unique, valuable information developed in preparing reports, studies, etc.
- It conveys unique, valuable information about your programs, policies, decisions, or essential actions.
- It conveys statements of policy or the rationale for decisions or actions.
- It documents oral exchanges (in person or by telephone), during which policy is formulated or related activities are planned or transacted.

- It adds to the proper understanding of the formulation or execution of actions or operations and responsibilities.
- It documents important meetings and facilitates action by service or department officials and their successors in office.
- It makes possible a proper scrutiny by auditing bodies external to the service or department.
- It protects the financial, legal, and other rights of the Government and of persons directly affected by the Government's actions.

Examples of Records:

Meeting Minutes	Functional Statements
Competency Folders	Position Descriptions
Timekeeping documents	Purchase Card transactions
Contracts	Recruiting and Staffing files
Emergency Action Plans	Tracking spreadsheets
Equipment Requests	Committee Records
Employee Folders	IPPS Invoices
Budget Planning	Blueprints & diagrams
Travel Vouchers	Maintenance Records

Getting Started

Records retention policies are in the Records Control Schedule (RCS) 10-1. FDA regulated studies have a different records retention requirement and litigation holds will also alter the retention schedule of certain records. Please see end of this section for links to resources.

1) Identify the Facility Records Manager. Determine who will be the Records Liaison for Research. Depending on size, you may identify several individuals.
2) Locate all temporary storage locations within Research and Medical Center space where research data/information are being stored.
3) Identify electronic storage locations of research data or information
    a. Who controls access to these folders?
4) Create a spreadsheet with required information for tracking all hard copy and electronic records, unless you have an electronic protocol management system that can track this information for you. You will also want to check with your facility's Records Manager to ensure all required elements are being tracked.
   At a bare minimum, one will want to ensure the following is being recorded:
    a. Date of Inventory - Date initial inventory form was prepared, or date last updated
    b. Person conducting the inventory - Name and telephone number
    c. Record Title and Record Series - Give each series a title for brief reference or include the generally accepted title
    d. Record Description - A concise description of the records, which may include the purpose, use, and subject content of the records
    e. Records Control Authority - Records Control Schedule (RCS) 10-1, GRS, National Archives
    f. Item # - Item No. specified in the applicable records schedule

g. Disposition - If the series has an approved disposition authority, list the schedule as described on RCS 10-1, GRS, etc., i.e., Destroy after 1 year. If the series has no such authority, list the files as "unscheduled," and make sure they are preserved.
h. Location - Give the precise location of the series, File Cabinet #, etc.
If the series is located in more than one office, indicate multiple locations.
i. Arrangement - Indicate the arrangement of the records, i.e., alphabetic, numerical, etc.
j. Date Range - The earliest and most recent dates of the records in each series. These are needed to schedule records, and to determine when to cut off, or break them and transfer them to records centers or agency storage facilities.
k. Medium - Indicate whether the record medium is paper, CD/DVD, diskette, electronic, audiovisual microform, maps/drawings, or a combination of these.
l. Cutoff - To cut off records means to break, or end, them at regular intervals to permit their disposal or transfer in complete blocks to permit the establishment of new files. Indicate how often the records are cut off and when the last cutoff occurred.
m. Reference activity - Rate the reference activity of a paper record series, after the regular cutoff, by placing it in one of three categories:
    i. Active (used more than once a month)
    ii. Semi-active (used less than once a month)
    iii. Inactive (not used for current operations)
n. Duplication - Indicate duplication in form or content. It can exist in the following ways:
    i. Copies may be in the same organizational unit or elsewhere in the agency. The copies may contain significant differences or notations.
    ii. Similar data or information may be available elsewhere in the agency either physically duplicated or in summarized form.
o. Volume - The volume of records in inches/feet, where possible. When inventorying audiovisual, microform, cartographic, and related records, provide an item count (e.g., 1200 prints, 3500 negatives) where appropriate.
p. Legal Status - If the records qualify as vital records, specify whether they would be needed in an emergency (emergency-operating records) and whether they are needed to document legal or financial rights, or both. Also, indicate whether they are the originals or duplicates.
q. Restrictions on access and use - Indicate any restrictions on access to, and use of, the particular series. Such restrictions may result from statutes, executive orders, or agency directives. Common types of restrictions are:
    i. Privacy Act restrictions
    ii. National security restrictions
    iii. Freedom of Information Act restrictions
    iv. Other applicable restrictions that may be specific to the agency

5) Create 7468s for all records that are archived on-site as well as those off-site. This form is to track current records as well as to certify destruction once records have reached their cutoff date.
6) Ensure the Initial Review and Continuing Review documents for all research projects have PIs disclose where they are storing their research data, both hard copy and electronic.
7) Submit the spreadsheet annually to the Facility Records Manager, or as requested
8) Submit weekly reports to the Facility Records Manager of all temporary storage locations of records that are archived locally
9) Upon study closure or the departure of a principal investigator, ensure study closure forms prompt the principal investigator to identify all their data locations and create a process to transfer that data, hard copy and electronic, to a secure location for retention until the cutoff date.

Develop a local policy that describes the purpose, scope, definitions, responsibilities, and procedures for carrying out the records management program. Currently, off-site storage of VA records is approved at NARA locations and is coordinated through the facility's Records Manager. Payment for the storage of records is also funded by the facility. For additional details regarding long term off-site storage, please meet with your facility's Records Manager, if your facility does not have a records manager, please contact the VHA HIM Records Management Council by email at VHAHIMRMC@va.gov. They can assist in setting you up with a mentor and providing additional guidance on how to get a contract initiated for long-term off-site storage.

Policies, Resources, and Helpful Links

FDA Records Retention
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62 and
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.180

General Records Schedule
https://www.archives.gov/records-mgmt/grs.html

Guidance on ORD's New Record Control Schedule
https://www.research.va.gov/resources/policies/guidance/rcs-guidance.pdf

Health Information Management website for records management
https://leaf.va.gov/VISN3/630/records_management/

Office of Management and Budget (OMB) Circular A-123
https://obamawhitehouse.archives.gov/omb/circulars_a123_rev

OMB Circular A-130 https://www.federalregister.gov/documents/2016/07/28/2016-17872/revision-of-omb-circular-no-a-130-managing-information-as-a-strategic-resource

Title 44 U.S.C. Chapter 31
http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title44-chapter31&saved=%7CKHRpdGxlOjQ0IHNlY3Rpb246MzEwMSBlZGl0aW9uOnByZWxpbSkgT1IgKGdyYW51bGVpZDpVU0MtcHJlbGltLXRpdGxlNDQtc2VjdGlvbjMxMDEp%7CdHJlZXNvcnQ%3D%7C%7C0%7Cfalse%7Cprelim&edition=prelim

Title 44 U.S.C Chapter 33
http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title44-chapter33&saved=%7CKHRpdGxlOjQ0IHNlY3Rpb246MzMwMSBlZGl0aW9uOnByZWxpbSkgT1IgKGdyYW51bGVpZDpVU0MtcHJlbGltLXRpdGxlNDQtc2VjdGlvbjMzMDEp%7CdHJlZXNvcnQ%3D%7C%7C0%7Cfalse%7Cprelim&edition=prelim

Title 44 U.S.C. Chapter 35
http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title44-chapter35&saved=%7CKHRpdGxlOjQ0IHNlY3Rpb246MzUwMSBlZGl0aW9uOnByZWxpbSkgT1IgKGdyYW51bGVpZDpVU0MtcHJlbGltLXRpdGxlNDQtc2VjdGlvbjM1MDEp%7CdHJlZXNvcnQ%3D%7C%7C0%7Cfalse%7Cprelim&edition=prelim

Title 36 CFR Chapter XII, Sub Chapter B
https://ecfr.io/Title-36/CXIIsubchapB

Storage Standards Toolkit
https://www.archives.gov/records-mgmt/storage-standards-toolkit
Develop system for managing records for new, existing, and closed studies.

The following directives and handbooks can be found at VA Publications

VA Directive 6300, Records Management

VA Handbook 6300.01

VA Handbook 6300.2.

VA Handbook 6300.4.

VA Handbook 6300.5.

VA Handbook 6300.6.

VA Handbook 6300.8.

VA Handbook 0320.

VHA RCS 10-1.
https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf

VHA Directive 1907.01.
https://www.va.gov/vhapublications/publications.cfm?Pub=1

SECTION 25 – Financial Conflict of Interest

The FCOI Form

As a Federal agency, VA's policies on FCOI must be consistent with requirements for government employees of the Executive Branch published by the Office of Government Ethics (OGE) established by the Ethics in Government Act of 1978. OGE is the agency providing overall direction, oversight, and accountability of Executive Branch policies designed to prevent and resolve conflicts of interest.

Currently the FCOI disclosure form can be found on ORD's Tech Transfer Program website (Research Financial Conflict of Interest Statement).

The FCOI Form needs to be completed by the Principal Investigator, Co-PI, or Co-Investigators participating on the project. The FCOI Form is project specific and is completed with a new project submission but also must be re-done annually.

In general, researchers need to understand that the rules for Federal employee researchers are different from the rules in academia. Federal employees are subject to criminal conflict of interest statutes as well as the Standards of Conduct regulations. These rules, in simple terms, prohibit Federal employees from participating in official VA matters (e.g., research) if the employee has a personal financial interest or relationship that might affect their service to the Government are they acting in the best interest of the public, Veterans and the Department or is there some element of benefitting themselves or others. For the VA employee, the close relationship with the university affiliate only increases the potential to have an outside interest that might disqualify someone from conducting research at VA. One caveat – the mere existence of an outside interest does not automatically disqualify someone from a certain study – the determination is fact-driven, and existence of an outside interest might mean that a consult with OGC Ethics Specialty Team (EST) is in order. OGC has tools to manage some interests that would otherwise be disqualifying.

Under VHA policy, VA investigators must have a VA appointment (with or without compensation) or be detailed or appointed under the IPA. All VA investigators are therefore subject to the Government ethics rules be they at VA under a full-time or part-time appointment, salaried or WOC or under an IPA. Contractors may not serve as investigators but may support research activities at the VA if it is in the terms on the contract.

Interests and relationships that might signal a need to contact VA OGV Ethics Team include:

- an outside entity that is funding/sponsoring the study or that owns or has licensed rights to inventions that are involved in or affected by the study ("affected" should be initially thought of in a very broad sense) – if the researcher or his spouse or minor child:
    - has a financial interest in the company through ownership, stock holdings (including publicly traded companies), being general partner;
    - has a fiduciary responsibility toward the company because of service as officer/director/trustee (usually on the board of directors);
    - is an employee, consultant, contractor, agent, or otherwise does business with the outside entity (e.g., speaker's bureau, member of scientific advisory board, consultant) (or if the researcher has held such a position within the past year); or
    - is negotiating or has an agreement for future employment with the entity

- inventions are involved in the study – either the study is further research into the invention or will affect the value of the invention (e.g., make it more-or-less likely to be commercialized) and the invention is:

- made by the researcher,
- owned by the researcher, or
- owned by someone or some entity other than VA (including if that entity is the university affiliate) in which the researcher has a relationship.

The Federal Technology Transfer Act at section 3710a, subparagraph (b)(3)(C), of title 15 United States Code, permits a Federal employee, under a Cooperative Research and Development Agreement (CRADA), to participate, as part of official duty, in effort to commercialize an invention made by the researcher while in the employment or service of the Government. This means that with supervisory approval and after putting in place a CRADA, and if necessary, a waiver of the criminal conflict of interest statute (208 waiver through EST), a VA researcher who has made an invention may assist the outside company that has licensed the invention in the commercialization effort by providing scientific and/or technical expertise or serving on the scientific advisory board. However, such assistance does not extend to activities related to the management of the outside company or to the promotion and/or marketing of its products to the public, in general. OGC Ethics should be consulted to determine if a 208 waiver is necessary.

Additional information on VA ethics can be found at
https://vaww.ogc.vaco.portal.va.gov/law/ethics/SitePages/Home.aspx

For an ethics consultation, email:

- **OGCNorthAtlanticEthics@va.gov** for CT, DC, DE, MA, MD, ME, NC, NH, NJ, NY, PA, RI, VA, VT, WV
- **OGCSouthEastEthics@va.gov** for AL, FL, GA, KY, Puerto Rico, SC, TN
- **OGCMidwestEthics@va.gov** for IA, IL, IN, KS, MI, MN, MO, NE, ND, OH, SD, WI
- **OGCContinentalEthics@va.gov** for AR, CO, LA, MS, MT, OK, TX, UT, WY
- **OGCPacificEthics@va.gov** for AK, AZ, CA, Guam, HI, ID, NM, NV, OR Philippines, WA

208 Waivers

It may be possible to obtain a 208 Waiver and authorization that allows the researcher to participate in research from which they would otherwise be disqualified, absent such a waiver, because of their financial interest in the matters. The researchers will submit the information below to their VA Ethics official who will work with them on a waiver. If approved by the Federal Government Office of Government Ethics, the waiver will be processed through the ACOS for Research and signed by the MCD. The current process is outlined here.

SECTION 26 – Publishing VA Research

Checklist for publishing VA research (funded by VA or used VA resources)

- Much of this information is covered in Publication Notification Process for VA Investigators where you can hyperlink to various informational sources.
- Note that the ORD service funding the study may have additional requirements; contact the specific service or review the ORD website for more information.
- **Tech Transfer Issue to consider:** Publication of VA Research to include manuscripts, posters, articles, or posting on a publicly available website which incorporates a description of the invention is considered a public disclosure. Public Disclosure of an invention prior to filing a patent application may prevent the VA from obtaining patent protections for the invention. Before publishing any VA works email the VA's Technology Transfer Invention Disclosure distro at vattid@va.gov to ensure any potentially patentable subject matter is properly documented, filed, and recorded in accordance with VHA Policy.
- **Acknowledge VA support Acknowledge VA employment in the manuscript:**
    - If the work was funded by VA, include this statement:
        - "This work was supported [or supported in part] by [type of award, e.g., Merit Review, Career Development Award, Pilot Project) Award # [award/project number, e.g., I01 RX000123] from the United States (U.S.) Department of Veterans Affairs [as applicable, indicate Biomedical Laboratory Research and Development Service; Clinical Sciences Research and Development Service (mention the CSR&D Cooperative Studies Program if applicable); Rehabilitation Research and Development Service; or Health Services Research and Development Service]."
    - If VA only provided resources (e.g., facilities or patients), include this statement:
        - "This material is the result of work supported with resources and the use of facilities at the [name and location of VA medical facility]."
- **Acknowledge VA employment in the manuscript**
    - Acknowledge employment of VA authors with VA title, name of VA medical facility, city, and state.
    - Academic affiliate appointments can also be listed, but if research was funded only by VA, the VA affiliation should be listed first.
- **Include DVA/US Government disclaimer in the manuscript**
    - Include this disclaimer: "The contents do not represent the views of the U.S. Department of Veterans Affairs or the United States Government."
- **Include NCT number in the manuscript**
    - If your publication concerns a clinical trial or observational study that was registered on clinicaltrials.gov, include the NCT number in the publication. This allows the clinicaltrials.gov website to link your paper to the trial registration.
- **Notify VHA Research Publications**
    - Alerting VA Research Communications about upcoming publications or presentations is particularly important when the topic is newsworthy, and VA can develop some productive media relations or when the topic is controversial, and the assistance of Public Affairs is likely to be needed.
    - Publications can be reported on-line at http://vaww.pubtracker.research.va.gov . In the near future, publication notifications will transition to VAIRRS (IRBNet)

- **Deposit manuscript in PubMed Central if the research was ORD-funded research**
    - For specific instructions, see: http://www.ncbi.nlm.nih.gov/pmc/
    - Deposited manuscripts must be made available to the public in PubMed Central no later

than 12 months after their publication in a journal.

- Some journals have an arrangement by which they will deposit the paper in PubMed Central automatically. Participating journals are listed here: https://www.ncbi.nlm.nih.gov/pmc/journals/
- Unless you are sure that the journal is posting, the author must post it. The following link to a flow chart on "How Papers Get Into PMC" includes helpful information to assist authors in working out how their papers may get into PMC:
  - https://www.ncbi.nlm.nih.gov/pmc/about/submission-methods/

SECTION 27 – Communications

Working with the Public Affairs Office and ORD Communications

VA Research is probably the "best kept secret" in VA and probably in all Federal organizations. Research is the one bright area that continues to allow VA to put its best foot forward. Each VA Medical Center should have a Public Affairs Office that is tasked to be an interface between the VA, its constituents, the community, and the lay media. In many instances, the "hot" scientific discoveries or newsworthy items are first picked up by the university affiliate (if there is an affiliated school with the local VA). Many of the up-and-coming discoveries that could have wide potential benefit in medicine are first reported at large national and international scientific meetings. These newswires are funneled through the university affiliate even if the investigator and investigative team making the discovery has a VA affiliation. The VA is usually the last to be acknowledged for positive items but generally the first to be singled out for untoward events.

VA Investigators should be aware of the VA Public Affairs Office and usually the specific contact in that Public Affairs Office when it is anticipated that a newsworthy item will surface. If contact with the Public Affairs Office is unknown to the Investigator, the Investigator should contact the Research Office, either the Associate Chief of Staff for Research or the Administrative Officer / Health Science Officer to put him/her in contact with the correct person in the Public Affairs Office. In many instances, the VA Public Affairs Officer has a direct line to the university affiliate Public Affairs Office so that joint announcements or releases can be made giving credit to both the VA and the affiliate for dual appointees and their discoveries.

Why is it important to be sure that VA receives credit for discoveries that emanate from VA research? Positive news coverage and acknowledgement of VA science will continue to be a positive tool to ensure that those having control over the VA research budget will have data to continue to support VA research. VA constituents who read or hear about these discoveries and medical advances made by VA Investigators will also be welcomed lobbyists and positive voices for VA research (these include VA patients and Veterans Service Organizations). In order to assist the Office of Research and Development, Veterans Health Administration to be aware of publications, presentations, interviews of VA investigators, or other newsworthy events, this information can be entered into the VA ORD SharePoint Pubtracker site: http://vaww.pubtracker.research.va.gov.

Interestingly, despite having an annual Research Week celebration, many employees of an individual medical center do not know the existence of VA research or may know very little of the discoveries ongoing at their medical center. Thus, some Public Affairs Offices put out periodical communications within the medical center highlighting VA research so that all employees can be engaged in the positive features of a research program.

On many occasions, the VA Public Affairs Office may be involved in helping to curb negative VA research image (especially with animal rights groups) by presenting the facts about how VA research has contributed to advancing medical knowledge and contributing to diagnostics and cures that benefit not only VA patients, but all patients afflicted with common diseases that are also experienced by VA patients. Public Affairs Office usually reports directly to the Medical Center Director. Having an open line of communication between the Research Office and the Public Affairs Office allows for the Director to be aware of positive aspects of his or her Medical Center, but also gives the Medical Center Director a head's up for "prickly" items involving Research.

SECTION 28: Useful Tools and Websites

VHA DIRECTIVES AND HANDBOOKS and PROGRAM GUIDES

ORD utilizes directives, handbooks, and program guides to disseminate policy. These cover a lot of topics and are subject to change.

To find policies, it is best to start at the ORD website:

https://www.research.va.gov/resources/policies/default.cfm

However, if you know the Directive or Handbook number you can search using the VHA publications page:

https://www.va.gov/vhapublications/index.cfm

Useful Web Links

Description	Web Address	Comment
VA Intranet Forms	http://vaww.index.va.gov/search/va/index.jsp	Click on VA Forms, VA/VHA Publication
Research Resources	https://www.research.va.gov/resources/default.cfm	(Policies, publications, contact list, directories, training)
ORD Homepage (Intranet)	http://vaww.research.va.gov/default.cfm	
ORD List of RFA's and Program Announcements	http://vaww.research.va.gov/funding/rfa.cfm	Merit Proposals, etc.
ORD Electronic submission information	http://vaww.research.va.gov/funding/electronic-submission.cfm	
ePROS	ePROS - Enterprise Protections, Regulatory, Outreach, and Systems (va.gov)	
VA Central IRB	http://www.research.va.gov/vacentralirb/default.cfm	
The Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html	
AAALAC	http://www.aaalac.org/	
AALAS	http://www.aalas.org/	
IPPS	https://vaww.ipps.fsc.va.gov/	Invoice processing system
Concur Travel Solutions	https://cge.concursolutions.com/ ***or*** VA Identity and Access Management System (IAM)	VA Travel processing
ePROMISe	http://epromise.research.va.gov/epromise/login.htm	
eRA Commons	https://commons.era.nih.gov	
JIT	https://vaww.gateway.research.va.gov/jit/	
PRIM&R	www.primr.org	Advancing ethical standards in science and research

SRA (Society of Research Administrators)	www.srainternational.org	Professional development organization for research administrators

Research Calendar

Broad category	Discipline	Regulatory item	Point of Contact	Latest approval/ Review	Review Schedule
Regulatory visits	Animal research	AAALAC	AO/ Veterinarian		Every 3 years
Regulatory visits	Safety	Annual AWE rounds	AO/ Research Safety		Annually
Regulatory visits	Compliance	ORO RCO	AO/RCO		
Regulatory visits	All	ORO Comprehensive Review	AO/RCO		Every 5 years
External reports/doc/approvals	Animal Research	OLAW Assurances	IACUC Chair/Veterinarian		Every 4 years plus annual review every Dec.
External reports/doc/approvals	Animal Research	Semi-Annual Inspection Report	IACUC Chair/ Veterinarian		Semi-annual
External reports/doc/approvals	Animal Research	Annual USDA Report	Veterinarian/AR F Supervisor		Every Dec
External reports/doc/approvals	Animal Research	VMU Central Office Report	Veterinarian/AR F supervisor		Every Dec
External reports/doc/approvals	Human Subjects	FWA	IRB Coordinator		Update as Needed or every 5 years.
External reports/doc/approvals	Human Subjects	IRB Membership Listing	IRB Coordinator		Update as Needed
External Meetings	VISN Oversight	VISN Research Roundtable	ACOS/AO		Quarterly
External Agreements	MOU	VA Central IRB MOU	R&DC/CIRB coordinator		Annual R&DC
External Agreements	MOU	Affiliate IACUC MOU	IACUC/ ACOS		Annual R&DC
External Agreements	MOU	Affiliate Data Security MOU	ACOS/AO		Annual R&DC
External Agreements	MOU	Affiliate Safety MOU	ACOS/AO		Annual R&DC

External Agreements	MOU	Non-Profit MOU	PREF ED/ ACOS		Annual R&DC
External Agreements	MOU	Cytometry Core MOU	AO/ ACOS/IFI		Annual R&DC
Internal document	Human Sub	HRPP IRB SOP	IRB coord		yearly review
Internal document	R&D	Research MCM	AO		yearly review
Internal document	Safety	Chemical Hygiene Plan	Research Safety		yearly review
Internal process	Safety	Hazardous Chemical inventory + attestation from PIs	AO		semi-annual
Internal process	Safety	Semi-annual Bldg XX walk-through by SRS	SRS Chair/coord		every 6 months
Internal process	Safety	Annual Emergency and Disaster Preparedness Plan	RSO		every year
Internal process	Safety	Annual Safety/Security Drills (access, chemical, security)	Police, Safety		every year
Internal process	Safety	Quarterly EOC rounds	Research Safety		quarterly
Internal process	Safety	Review of weekly Bldg XX access	AO		weekly + monthly
Internal process	Safety	Weekly RSO walkthrough with monthly report at SRS	Research Safety		weekly + monthly
Internal process	Safety	SRS review of Research Bldg access	AO/SRS coord		semi-annual
Internal Process	Safety	Annual Review of off-site VA research	AO/ ACOS		Annual
Internal process	Research program	Performance Evaluation	AO		
Internal process	Research program	Mid-year Performance Evaluation	AO		
Internal process	Research program	Review submitted and active funding awards	AO/ ACOS/BA		
Internal process	Research program	Review research instruments	AO/ ACOS/BA		
Internal process	Research program	Review off-site research	AO/ ACOS		
Internal process	Research program	Review faculty MOU and effort mapping	AO/ ACOS		
Internal process	Research program	Review research budget	AO/ ACOS/BA		
Internal process	Research program	Research Equipment Inventory	AO/ ACOS Equipment Communications		

External reports/doc/approvals	Grants	SAM registration	AO/BA		

External reports/doc/approvals	Grants	RDIS II report	BA		Every Sept/Oct
External reports/doc/approvals	Grants	Pre-application and Submission deadlines - ISRM-SRG-Purviews-and-Review-Cycles.pdf (va.gov)	BA		See applicable RFA
Funding application	Grants	ShEEP/LAMB	AO/ ACOS		

Section 29: Comprehensive List of ACOS and AO R&D Responsibilities as Defined in VHA Directives and Program Guides:

Note: In limited cases as noted below the ACOS responsibilities listed below can be delegated to the AO R&D, or another individual such as a Deputy ACOS for those stations that have one. AO Responsibilities can in some cases be delegated to other Research Administrative Support Staff.

1200.01: Research & Development Committee

The Associate Chief of Staff for Research and Development (ACOS) (or Coordinator for R&D in a smaller facility) is responsible for:

(1) Serving as the Executive Secretary of the R&D Committee and providing administrative support, including correspondence, scheduling meetings, and responding to questions about the Committee.

(2) Notifying investigators, in writing, when a research project can be initiated, and the period for which the project is approved. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees and the R&D Committee. NOTE: The ACOS notification may be combined with the R&D Committee approval notice. If combined, the R&D Committee approval notice may be signed by the ACOS alone, or together with the R&D Committee Chair, per local policy. ACOS notification is not required for continuing review.

1200.02: Research Business Operations

The Chief of Research (ACOS or other title as appropriate) at the VA medical facility reports through the Chief of Staff to the VA medical facility Director. The Chief of Research must possess credible research and academic experience and maintains their own research activities. The Chief of Research is responsible for the effectiveness and efficiency of the VA medical facility research program, including:

1. Ensuring systems are in place to maintain compliance with research-related regulations and policies.

2. Appointing a VA medical facility Administrator for R&D and notifying the Director of Field Operations in ORD of the appointment; when there is a vacancy, detailing a person to cover this position until it can be filled.

3. Ensuring that VA investigators and staff receive appropriate resources such as space, access to data and other administrative resources to conduct VA research projects.

4. Working with the VA medical facility R&D Committee to provide scientific guidance to VA investigators, as needed.

5. Ensuring that a proper Veterinary Medical Unit is available prior to submitting or initiating any research involving animals. ***NOTE:*** *See VHA Handbook 1200.07, Use of Animals in Research, for detailed information regarding the animal program.*

6. Ensuring that all research personnel hold an official VA appointment from Human Resources Management Service (HRMS) (as a compensated, full-time, or part-time employee, WOC or IPA) prior to conducting or engaging in VA research activities, and that the individuals maintain their appointment while conducting or engaging in VA research activities.

7. Ensuring that all requests for WOC appointments for research have been appropriately justified to work on

research projects. ***NOTE:*** *Individuals working under a contract with VA or on a fee-for-service basis cannot conduct research under a separate WOC appointment for the same duties. A VA supervisor must be officially appointed for each WOC employee and may be a PI on whose study the WOC employee is working, a section Chief, the Administrator for R&D, or the VA medical facility Chief of Research.*

8. Ensuring the Research Service has access to all approved research protocols, amendments, consent document templates and other documents submitted to a research review committee or subcommittee, and documents related to the actions of the research review committees; ensuring there is a records management plan that includes retention of research records. ***NOTE:*** *If the PI leaves the VA medical facility, the VA medical facility Research Service must ensure that all protocol files are stored securely per VHA Directive 6300(1), Records Management*.

9. Providing assistance to partnered VA medical facilities when a formal collaboration with another VA medical facility is established.

e. **VA Medical Facility Administrator for Research and Development.** The Administrator for R&D (AO-R, DRO, or other title as appropriate) at the VA medical facility supports the VA medical facility's research program by administering and managing the business operations of the program. Responsibilities of this position are dependent on the VA medical facility's needs and the scope and complexity of the research program. Responsibilities may be delegated to another qualified staff person within the VA medical facility Research Service. These responsibilities include but are not limited to:

1. Managing all VA medical facility research funds (0161 appropriation and General Post Fund donations) in coordination with the VA medical facility Finance Officer.

2. Ensuring systems are in place to manage budgets for individual VA-funded projects.

3. Reporting required financial and research project information in Research and Development Information System (RDIS), or the information system superseding RDIS, and ensuring its accuracy.

4. Tracking of all required activities or elements of the VA medical facility research program such as research personnel, research activities and educational requirements.

5. Maintaining the VA medical facility Research Service's Equipment Inventory List or ensuring it is maintained correctly by other Research Service staff or other office designated by the VA medical facility's local standard operating procedure.

6. Coordinating research personnel issues with HRMS.

7. Along with the VA medical facility Subcommittee on Research Safety, the Biosafety Officer, the Industrial Hygiene Officer, or the Chemical Safety Officer, overseeing research laboratory areas. ***NOTE:*** *For further details regarding the role of the Subcommittee on Research Safety, see VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research.*

8. Assisting with issues related to the Veterinary Medical Unit.

9. Coordinating any required site visits from VA and other agencies or organizations.

10. Coordinating all oversight activities and ensuring they are completed appropriately.

11. Assisting with developing and implementing the research components of the VA medical facility Emergency Preparedness Plan.

12. Ensuring that all VA medical facility research program safety and security issues are addressed.

13. Working with the VA medical facility's Chief Information Officer, the VA medical facility's Information Systems Security Officer and others, as needed, so that the Information Technology needs of the VA medical facility research program are met.

1200.07: VA Research with Animals

The VA medical facility Associate Chief of Staff for Research and Development (ACOS) is responsible for administering and managing the local VA research program, as described in VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019, and VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.

The ACOS may delegate specific tasks and responsibilities to the VA medical center Administrative Officer for Research and Development (AO/R&D) as necessary. For research with animals, administering and managing the local program generally involves, but is not limited to, the following:

(1) For a program with an internal IACUC, (a) Coordinating administrative support for the work of the IACUC. (b) Assisting the VA medical facility Director to ensure that the IACUC both has adequate administrative support and meets its responsibilities.

(2) For a program with an external IACUC,

(a) Ensuring communication between the external IACUC and the VA medical facility.

(b) Ensuring that information relevant to VA animal research is communicated to the R&D Committee, VA research administrators and VA facility leadership as needed for effective coordination of the actions of the external IACUC and the VA program.

(3) Ensuring that documents submitted for JIT processing are congruent with the projects that they are submitted to support. The ACOS and AO/R&D may delegate the evaluation of this congruency but remain responsible for ensuring that the documents accurately reflect the proposed work.

1200.08: Safety of Personnel and Security of Laboratories Involved in VA Research

Associate Chief of Staff for Research & Development. The ACOS (or Coordinator for R&D in small facilities) is responsible for:

(1) Overseeing the implementation of all requirements set forth in this directive.

(2) Ensuring creation and update of the facility RSSP that appropriately addresses research safety, and laboratory security, at the facility and in space occupied by VA under a legal agreement. For VA research conducted in laboratories located in approved off-site facilities such as affiliate universities, the ACOS must ensure that a process is in place to review research safety and security, and if necessary, provide feedback to the responsible party for the off-site facility on any deficiencies.

(3) Coordinating efforts and communication among all relevant officials, committees, and individuals to ensure the successful implementation of the RSSP.

(4) Putting mechanisms in place to ensure that access to VA research areas is monitored and evaluated regularly to prevent unauthorized persons from gaining access.

(5) Ensuring that research service provides the facility police service with the information and the support necessary to meet police responsibilities for research security. This includes: (a) Ensuring that all research areas are included in the routine assessment of the vulnerability of the facility to security breaches conducted by the police service. NOTE: This does not include off-site facilities that are not under a fully executed VA lease. (b) Supporting the performance of the routine security and incident response drills or exercises required by the Emergency Management Program or Safety Office. (c) Informing the facility police service of any changes in research affecting the facility's security needs.

(6) Notifying ORD and ORO when construction of any new BSL-3 research laboratory, renovation of any existing BSL-3 research laboratory, or reactivation of any inactive BSL-3 laboratory is planned.

(7) Notifying ORD and ORO when a BSL-3 laboratory will be inactivated or closed. 7 April 24, 2019, VHA DIRECTIVE 1200.08(1)

(8) Ensuring that there is a process by which the SRS is notified whenever space is decommissioned, or when the identification and disposal or decontamination of hazardous materials and/or equipment is required between uses.

(9) Establishing mechanisms to ensure that all personnel conducting VA research (including VA contractors, students, and visiting fellows, as well as those with VA appointments), comply with all VA standards for safety and security described in this directive and all other applicable ORD guidelines (https://www.research.va.gov/resources/policies/default.cfm).

(10) Ensuring that safety-related communications from ORD or other VA offices are distributed to appropriate local personnel, in a timely manner, upon receipt.

(11) Working with the SRS as needed to ensure that research activities stop when the SRS imposes either a safety hold or suspension until the hold or suspension is rescinded.

(12) Meeting the responsibilities assigned to the ACOS in the RSSP.

(13) Identifying an individual qualified through training or experience and delegating Research Chemical Hygiene Officer responsibilities to that person if the medical facility does not have someone specifically appointed to that role.

(14) Appointing a Biological Safety Officer if the VA research program involves the use of recombinant or synthetic nucleic acid molecules at BSL-3, or large scale (greater than 10-liter cultures) research on or production involving recombinant or synthetic nucleic acid molecules, as NIH Guidelines require.

(15) Reviewing and approving requests for a CDC or APHIS laboratory registration number and Certificate of Registration, as required, before VA research laboratories at the facility may receive, transfer control/ownership to another individual, or use select agents or toxins.

1200.18: Determination of Rights for Inventions and Discoveries

The VA medical facility ACOS/R is responsible for:

(1) Ensuring that all VHA employees involved in research at their VA medical facility are educated about, and comply with, this directive and Federal regulations directed to 5 October 6, 2023, VHA DIRECTIVE 1200.18 VA's Invention Disclosure process, and complete the TTP online course each fiscal year. See paragraph 11 of Directive.

(2) Reviewing and approving all Invention Disclosure and VA Invention Certification forms submitted by VA employees at the VA medical facility along with the supervisor(s) of the inventor(s).

(3) Maintaining a registry of personnel authorized to participate in VA research at the VA medical facility, including

start and end dates of research employment or appointments and the academic affiliation(s) for DAPs, as applicable.

(4) Compliance with IP-related Records Management requirements in paragraph 12 of Directive.

(5) Ensuring a WOC IP Agreement is signed by the VA and each WOC employee prior to initiation of WOC duties.

1200.19: Presentation of Research Results:

The ACOS (or Coordinator for Research in a smaller VA medical facility) is responsible for:

(1) Ensuring that VA investigators know the guidelines for how and when to notify ORD Communications staff.).

(2) Ensuring that VA investigators know their responsibilities for acknowledging VA support in publications and presentations.

(3) Ensuring that VA investigators know their responsibilities to provide public access to publications . NOTE: Procedures for providing notification, and required elements of information, can be found on the ORD Web site at: http://www.research.va.gov/resources/policies/pub_notice.cfm.

Program Guide 1200.15: Eligibility for VA Research Support

The ACOS for R&D is responsible for informing the facility Director and the Director of the appropriate research service of any change in the PI's status (for example, if a PI's VA employment status falls below 5/8 time). Written communication to the appropriate research service Director must come from the facility Director with the endorsement of the facility ACOS for R&D and the facility Chief of Staff.

Section 30: AO Duties

Note: Some of these duties are handled by other members of the Research Office but an understanding of them still needs to be done to answer questions that arise, to make informed decisions and to be prepared for employee turnover.

- **Human Resources**
    - Hiring Actions and understanding hiring authorities – MSA, Schedule B, Competitive Recruitment
    - Positions Descriptions – Utilizing PD library, understanding PD series, grade levels and qualification standards, writing new PDs, process for submitting PDs to classification (LEAF).
    - Functional Statements for Nurses
    - Extensions – Process for extending term appointments on MSA or Schedule B authorities.
    - Terminations – What to submit, preparing for leave payouts, watching employee and project end dates.
    - Utilizing and having access to programs/SharePoint
        - PBI
        - RDRM
        - HRMACS SharePoint
        - HR Smart (MSS)
    - Performance Appraisals
        - ePerformance
        - Different phases of performance appraisals – timeline for completion
        - Unsatisfactory performance – how to handle
        - Process for awards
    - Conduct Issues
    - Reasonable Accommodations
    - IPA's – who can be on an IPA, paperwork involved, process.
    - WOC's – signing LEAF requests, who can be on a WOC, paperwork involved, process.
    - Signing annual renewals of Functional Statements.
    - Yearly competency assessments.
    - All Employee Survey

- **Finance/Budget**
    - Knowledge of programs. How to understand information and access each:
        - WinRMS – Monitor investigator account status.
        - Status of Allowance – how to view at the fund control point, program, and appropriation level
        - VISTA – running balances of fund control points, looking up purchase card orders, IPA's, contracts to see status, approve purchase card orders
        - IPPS – certifying invoices and checking obligation amounts, invoice status, etc.
        - VSSC – A lot of useful tools to manage day to day budget.
        - RAFT – Project Management. Look up project funding, end dates, pink sheets, and report expenditures
        - ACCS – View funding coming into facilities
        - US Bank – approve purchase card transactions
        - Project Modification requests – when to request redistributions
        - ORD Finance SharePoint – Recorded trainings.

- Purchase Card Approver
    - Approve purchase card transactions in VISTA and US Bank. Know what to look for prior to approving.
- Travel Approver
    - Approve both travel authorizations and vouchers in Concur.
    - Know regulatory rules that are allowed regarding per diems, tipping, transportation, etc.
    - Signing Trip Tickets
- Certify Invoices
    - Certify invoices for contracts, IPA's, core facilities, and patient reimbursements.
- Reimbursements
    - Types
    - MOU's and Bills to NPC (0161X2)
    - Bills to Affiliate and other external entities (0161R1)
    - How Reimbursements come into the facility and processing of them.
- Cost Transfers – Understanding when to use them, closing out prior year dollars, etc.
- G-Invoicing
    - IAA's with other agencies (CDC, NIH)
    - Reimbursements to pharmacy, laboratory, etc.
- CDA Salaries
    - Requesting excess or sending back surplus when report is requested by Sara Clark each year.
    - Physician CDA – cost transfers with Med Center

- **<u>Committee Management</u>**
    - IRB
        - IRB
        - Monitoring status of IRB submissions, checking workflow
        - Monitoring project submissions into IRBNet and R&D Committee review.
        - Managing collaborative research.
        - External IRBs
        - Serving as liaison with external IRB's.
        - Completing checklist prior to submission to external IRB to ensure informed consent has required language.
        - Understanding process with each external IRB and how it flows into R&D Committee. The reviews that are needed prior to R&D.
        - Completing annual institutional worksheet for NCI IRB.
        - VA Central IRB
        - Serving as liaison with VA Central IRB.
        - How to submit project in IRBNet to VA Central IRB. What to review prior to submission.
        - Understanding VA specific regulations
        - Monitoring MOU's and SOP's with each IRB.
        - Maintaining Federalwide Assurance (FWA).
        - Special approvals – Non-Veterans, Pregnant Woman, Children, International Research, etc.
    - IACUC –

        - Annual Reports
            - OLAW
            - USDA
            - VA
            - AAALAC
        - OLAW – Submit new assurance for review every 4 years.
        - AAALAC Accreditation every 3 years.
        - MOU with affiliate for Animal Care (if applicable)
    - Safety
        - IBC Annual report
        - Monitoring Access to Research Areas
    - Conflict of Interest and Outside Compensation
    - R&D Committee
        - Annual Subcommittee review
    - Annual Director's Checklist
    - Recruitment Only Studies – Approval process.

- **Merit Review Management**
    - Submission of LOIs, merit reviews, CDA's etc.
    - Just-in-Time process
        - Requesting 8ths for new physicians
        - Monitoring the 180 days to completion
        - Hiring new PhD investigators and the process with HRMACS
        - Selecting start dates
    - Project Modifications (including clinician bridge funding)
    - Monitoring end dates
    - Clinician Science Awards – Monitor when progress reports (cost extension project mod) are due for CSI and SCI awards.
    - Research Career Scientist Awards

- **Training Compliance**
    - Tracking compliance of research personnel
    - TMS
    - CITI

- **Timekeeping**
    - Approving leave, premium pay requests, and tour of duty changes
    - Certifying timecards.
    - Monitoring time off and ensuring leave is put in.

- **ePromise/RDIS Report**
    - This is the report that brings VERA funds into the hospital.
    - Enter all projects approved by R&D Committee throughout the year and ensure funding codes are correct.
    - Verify in September that all projects are entered, and any closed projects are finalized.
    - Gather funding information and submit by deadline of Nov. 15th.

- **Equipment Inventory**

- Utilizing Maximo.

- **Records Management**
  - Ensuring records are entered into the Records Management Repository.
  - Disposing of records – filling out form 7468 prior to destruction.

- **IT Items**
  - Approving IT Tickets
  - Approving Remote Access
  - Research website
  - Research SharePoint.

Section 31: Listing of Sites the AO Needs Access To.

AO List Serv – e-mail to Antonio.Laracuente@va.gov
AO Directory – e-mail to Art@va.gov
Merit Review Submissions

- **eRA Commons =** Commons | Home (nih.gov)
- **Grants.gov =** Home | GRANTS.GOV
- You will want to create an account - How to Create a Grants.gov Account and Link to a Login.gov Account – Grants.gov Community Blog (wordpress.com)? Once you do that, complete step 4 where you add an "organization applicant profile." You will need your facility UEI number.

HR
HR Liaison – Send request to Antonio.Laracuente@va.gov. This will give you access to LEAF, PBI, and SharePoint Access to HR Smart Manager and AO Role – https://hris.va.gov/portal/

Budget –

- **IPPS -** https://hris.va.gov/app/ui/page/content-page
- **G-Invoicing -** GINV PROD (treasury.gov)
- **WinRMS**
- **VISTA**
- **ACCS -** Home (va.gov)
- **RAFT -** RAFT Login (va.gov)
- **Concur Travel -** Sign in to Concur | Concur Solutions
- **VSSC –** Agreements Page (va.gov)
- **US Bank –** Welcome to Access Online (usbank.com)
- **ORD Field AO and Finance Management Resource SharePoint and e-mail group=** ORD Field Administrative Officer and Financial Management Resources (sharepoint.com)

Projects

- **IRBNet** – Welcome to IRBNet
- **ePromise -** ePROMISe -- Login (va.gov)
- **Records Management -** RM: All Entries - Page 1 (va.gov)
- **CITI -** Research, Ethics, and Compliance Training | CITI Program
- **FWA -** FWAs | HHS.gov

IACUC Annual Reports

- **OLAW -** Annual Report to OLAW | OLAW (nih.gov)
- **AAALAC -** http://www.aaalac.org
- **VA VMU -** U.S. Department of Veterans Affairs (va.gov)
- **USDA -** Submit Research Facility Annual Reports | Animal and Plant Health Inspection Service (usda.gov)

IBC Annual Report - https://ibc-rms.od.nih.gov/Contents/IBC_HOME.aspx?loggedout=yes

Personnel

- TMS - TMS 2.0 - SSOi PIV Login
- VATAS - Landing | GovTA (va.gov)

Equipment –

- Maximo – MAXIMO Start Center (va.gov)