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OVERVIEW OF VA RESEARCH

Medical and Prosthetics Research and Development in VHA is an intramural program administered by the VHA Central Office, Office of Research and Development (ORD) and conducted at VA medical facilities nationwide under the authority of Title 38 United States Code (U.S.C.), 7303. The R&D program is an intramural program that spans the continuum from basic biomedical research through the translation of research into practice, emphasizing the health concerns of Veterans.

The mission of the R&D program is to discover knowledge and create innovations that advance health care for Veterans and the Nation. ORD accomplishes its mission through a number of mechanisms including setting policy; identifying ethical standards; developing and presenting educational programs; consulting with field research programs, their staff, and their investigators; supporting research through funding opportunities; and assisting facilities in complying with applicable requirements, guidance, and educational programs. In support of this mission, ORD strives to:

(1) Sustain a superior environment of inquiry conducive to the highest quality research, education, and patient care.

(2) Effectively integrate fundamental, clinical, and applied research to best meet Veterans’ health care needs.

(3) Effectively transfer research results to advance Veterans’ health care.

(4) Maximize VHA’s value as a national research asset.

(5) Lead and manage an effective and efficient research enterprise.

(6) Increase awareness and understanding of the value of VHA’s research contributions.

Values guiding all R&D efforts include: scientific excellence; the ethical conduct of research; protection of human subjects; the welfare of laboratory animals; the safety of those involved in the research program; and the security of both our research laboratories, other research resources, and research data.

Employees with part-time, seasonal, or uncommon tours of duty will be provided a proportionally equivalent amount of leave.
The VA Research and Development Program

The VA Research and Development program is an integral part of the health care mission of the Department of Veterans Affairs. The Agency – and the Congress who fund it – believes that an active research program improves the quality of care to Veteran patients. In some cases, this improvement is direct, as in the development of improved prostheses for wartime amputees or the study of the “Persian Gulf Syndrome”. More often, it is reflected in the benefit to patient care from advances in health care for all persons, as well as from the spirit of inquiry, which is integral to research. The opportunity to do research attracts some of the very best clinicians to the VA. Even those who don’t themselves carry out research benefit from being in an institution devoted to solving the problems of their patients.

The existence of the VA research program depends on the quality of its product and on credit to the VA for that product. Unless the public and the scientific community identify and credit the VA’s contributions, Congressional appropriations will shrink. It is important to realize that all research in the VA, including that supported by other sources than the VA itself, depends on the Congressional appropriation for its infrastructure.

The present VA Research and Development program has four distinct units, each with its own budget and Headquarters staff. They are:

**Biomedical Laboratory Research and Development**, by far the largest unit. It supports most of the traditional biomedical research carried out in VA medical centers.

**Clinical Science Research and Development Services**, which supports multi-hospital, patient subject clinical trials, and epidemiological studies related to any of the above Services. In these studies, biostatistical and epidemiological support and coordination are provided from centralized units.

**Health Services R&D Service**, which supports research in the delivery of health care.

**Rehabilitation R&D Service**, which supports research directed toward helping persons with disabilities to optimize their health and functional status.
Priority Areas of Research

Targeted or priority areas of research focus on Veteran specific or “Veteran-centric” areas of health care, not generally seen or dealt with on a broad scale in the private sector. These health care priorities include those related to returning combat Veterans (not necessarily in order of importance):

- Traumatic Brain Injury
- Post-Traumatic Stress Disorder
- Tissue Damage involving large areas due to blasts and projectile injury
- Spinal Cord Injury
- Prosthetics and Sensory Loss
- Military Occupational Exposures (e.g., Agent Orange and Middle East conflict exposures)
- Suicide Risk and Prevention
- Risky Behaviors including substance use disorders including tobacco, alcohol, prescription pain medications (e.g., opioids), and non-prescription street drugs
- Military Service, Post-Deployment and Veteran-related mental health disorders, cognitive problems, and other behavioral issues. Many Veterans have dual diagnoses of substance abuse and mental health disorders.
- Women’s Health
- Genomic and Personalized or Precision Medicine
- Chronic Metabolic Diseases and Syndromes, such as diabetes mellitus and pain, as well as the use of Complementary and Alternative Medicine approaches for treatment of these conditions
- Health Promotion and Disease Management
- Pain Management
- Access, Care Coordination, and Patient Centered Care
Research at the VA Greater Los Angeles Healthcare System (GLA)

It was during this early postwar period, in 1948, that the VA hospital at West Los Angeles became the site for one of the first research laboratories in the VA and recruited its first research investigators. At that time, the hospital was affiliated with USC and the College of Medical Evangelists (now Loma Linda School of Medicine). The first post war Chief of the Medical Service was Roger Egeberg, General McArthur's personal physician, later Dean of the School of Medicine at USC and still later Secretary of Health, Education and Welfare. In about 1949, faculty recruitment began for the new UCLA School of Medicine, and most found research facilities at the VA. When the school admitted its first students in 1951, the VA became its first clinical campus. Even after the UCLA Hospital opened in 1955, the VA continued to be one of the most important UCLA affiliates. UCLA faculty mixed freely with VA faculty, both on the hospital wards and in the research laboratories.

The Sepulveda VA Hospital opened in 1955, and was affiliated with UCLA from the beginning. Beginning in the 1960s, an important group of basic scientists, as well as clinician scientists, joined the Sepulveda staff and became the nucleus for a vigorous research program.

Both Sepulveda and West Los Angeles were early recognized for their excellence in geriatric research. When centrally recognized GRECCs were started in the late 1970s, both received GRECCs in the first round of reviews. Excellence in health services research led to a collaborative Health Services R&D Center of Excellence, led by Sepulveda and including members from the West Los Angeles and San Diego VAs.

Through the years, the research program at VA Greater Los Angeles has grown and flourished. VA investigators have contributed to virtually every field of medical science. Products have included the first imaging system for radioisotopes, the concept which led to the CT scanner, the nicotine patch, and major improvements in the drug treatment of psychotic patients. At present, there are active, peer review approved, projects in virtually every field of health-related research and development. These projects, and the research investigators responsible for them, are listed on the GLA research web site.
GLA Research Hall of Fame

Central Office GLA Research Investigator Awardees:

Biomedical Laboratory Research and Development Service Middleton Award Recipients:

1965  Lucien Guze, MD
1976  William Oldendorf, MD
1983  Sydney Finegold, MD
1992  George Sachs, DSc, MD
1993  Neil Kaplowitz, MD
2010  Jerome Siegel, PhD
2014  Yvette Taché, PhD

Health Services Research and Development Service Under Secretary's Award Recipients:

2001  Lisa Rubenstein, MD, MSPH
2011  Paul Shekelle, MD, MPH, PhD
2012  Elizabeth Yano, PhD

GLA Highlights

• Conceptual design of the CT scan by Dr. William Oldendorf a former Senior Medical Investigator at Brentwood.

• VA Wadsworth is known for the establishment of the first Dialysis unit in Southern California and the second chronic dialysis unit west of the Mississippi by Dr. Milton Rubini.

• Delineation of a clinical test to determine aluminum-related bone disease in dialysis patients by Dr. Jack Coburn

• Design and basic cell biological testing of the now widely used proton pump blockers for peptic ulcer disease Dr. George Sachs.

• Dr. Sydney Finegold is a world-renowned authority on the biology and taxonomy of anaerobic bacteria and has contributed significantly to the knowledge of these disease-producing organisms.

• The discovery of the Lig proteins of pathogenic Leptospira species by James Matsunaga and Tracy Young in 2003. The Lig proteins are the first adhesions and subunit vaccines to be described in pathogenic Leptospira species.
• The first species-specific identification of bacterial pathogens in human clinical fluid samples using an electrochemical sensor array by Joseph Liao and David Haake in 2006.

• 2011 A lab study presented by Greg Cole, PhD, and colleagues with VA and the University of California, Los Angeles, at the recent International Conference on Alzheimer’s Disease suggests that DHA—a type of omega-3 fatty acid linked to cardiovascular and brain health—may be a potent agent against dementia, but mainly for prevention and not for treatment.

• 2011 Drs. Naser Ahmadi and Ramin Ebrahimi have found a link between cardiovascular disease and post-traumatic stress disorder (PTSD).

• 2011 While investigating how stress affects gastrointestinal function, researchers Drs. Yvette Tache, Lixin Wang and Million Mulugeta, may have discovered a chemical compound that induces hair growth by blocking a stress-related hormone associated with hair loss.

• 2015 Drs. Scott Krahl, Ralph J. Koek, and Jean-Philippe Langevin performed the first-ever-trial of deep brain stimulation to treat posttraumatic stress disorder.
In the 1970s the Veterans Health Administration began planning to meet the challenges the aging World War II Veteran population would present. At the time the field of geriatric medicine was rather small, so to help grow the field and develop the infrastructure necessary to handle the complexities such a large influx of elderly patients would present the Geriatric Research Education and Clinical Centers (GRECCs) were developed. GRECCs were meant to attract scientists and health science students to the field of geriatrics in order to help increase the basic knowledge of aging, transmit this knowledge to health care providers, and improve the quality of care delivered to elders.

Each GRECC contains a research component, a education component, and a clinical component. Currently there are 19 GRECCs which compete for research grants to conduct basic laboratory research on the origins of aging and the diseases commonly associated with it as well as research how care is delivered to elders and the effects of rehabilitation. GRECCs help disseminate existing knowledge of geriatrics and new discoveries gained through research by offering regular educational events and products such as national conferences, regional conferences, telephone and video conferences, special fellowship programs to train physicians in geriatric medicine, conducting grand rounds and journal clubs, and producing peer reviewed papers and other materials such as newsletters, CD-ROMs, and web based presentations. The GRECCs also work with clinical staff in VA medical centers to provide care to elderly Veterans and demonstrate new and improved ways for that care to be delivered.

GRECCs are not meant to be large enterprises but centers of excellence with a core staff equaling 12 full time employees. Each year these small research units publish hundreds of peer reviewed articles, provide thousands of person hours in geriatric education, and are awarded millions of dollars in research grants. More significantly they provide care to the aging Veteran population while at the same time training many of the healthcare professional which will provide that care for years to come.
Dedicated to improving the long-term functional outcome of individuals with mental illness through innovative research, clinical care, and educational programs.

Overview

Beginning in 1997, Mental Illness Research, Education and Clinical Centers (MIRECCs) were established by Congress with the goal of bringing best practices in mental health care into the clinical settings of the VA. The MIRECCs conduct research, produce clinical educational programs and products, and enhance clinical treatment to Veterans.

Our Mission

The mission of the Desert Pacific MIRECC is to improve the long-term functional outcome of patients with chronic psychotic mental disorders, including schizophrenia, schizoaffective disorder and psychotic mood disorders. Psychotic illnesses are associated with a variety of perceptual and cognitive impairments that can impact vocational and social functioning, and quality of life. Unfortunately, available treatments are often only partially effective at addressing the many needs of afflicted individuals. Our approach to schizophrenia and other psychotic disorders is to improve understanding of the underlying neurobiology of these illnesses, to translate this improved understanding to improved clinical practices, and to assure that these improved practices are provided to Veterans. We approach this mission through an integrated program of research, education, and clinical programs aimed at translating findings from the research laboratory into improved clinical care. Moreover, our program spans the spectrum from basic brain biology to the organization of services for Veterans.

We believe that we have succeeded in creating a center program that fulfills these goals. All of our laboratories and units – Neuropsychopharmacology, Clinical Neuroscience, Treatment, Imaging, Data Management, Health Services, and Education and Dissemination – have developed a track record of accomplishment. Our programs have strongly supported VA’s adoption of a recovery model for severe mental illnesses. This support includes research programs that evaluate innovative pharmacological and psychosocial treatments for improving the community functioning of individuals with psychotic illnesses and programs that facilitate the implementation of recovery-oriented programs in VA clinical settings.
GLA Organization Here
What Constituents VA Research?

VA Investigator: A VA Investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employees, Without Compensation (WOC) employees, or individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. Individuals working under a contract with VA cannot conduct research under a WOC appointment.

VA Research: VA research is 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.

Trainee: Trainees are defined as those who are (1) Appointed under trainee authority and (2) Enrolled in one of two types of training programs:

- Enrolled in an accredited training program sponsored by an affiliated educational institution under a current and existing academic affiliation agreement or
- Enrolled in a VA sponsored training program (either accredited or non-accredited).

Trainee Research: Trainees who do not meet the definition of trainees under this Directive cannot participate in VA research unless the VA Medical Facility's Designated Education Officer seeks a waiver both

- from the Chief Academic Affiliations Officer or designee
- and the CRADO.

Students from unaffiliated academic institutions may not be permitted to conduct their student projects in VA or be given a WOC appointment for the sole purpose of conducting student research.
**PRINCIPAL INVESTIGATOR STATUS**

1. Principal Investigator (PI) status is preliminary approved by the ACOS for Research with final approval from the Research and Development Committee.

2. PI status may be granted to any investigator holding at least a part-time VA appointment. Potential PIs must first schedule a meeting with the ACOS for Research and provide a complete CV prior to the appointment. If granted status the PI will complete an Investigator Data sheet (RDIS, Part 1, Page 18) (copy of form is located in Appendix C) which will be submitted to ePROMISe Coordinator in the Investigator Services Center. The PI will be added into eRA Commons as being affiliated with VA Greater Los Angeles Healthcare System. If the PI is not in eRA Commons, an account (CID) will be created for the PI and will be notified by eRA Commons, via email, that an account has been established or is now affiliated with GLA.

3. A Without Compensation (WOC) investigator in most circumstances must have an identified VA investigator to serve as an “Administrative Investigator” on all protocols submitted by the WOC investigator. The VA investigator must agree in writing by memo to the Research & Development Committee to serve as an Administrative Investigator. The Administrative Investigator will have the responsibility for all laboratory safety issues and assurances in the research space utilized by the WOC investigator. Correspondence from Research Administration to the WOC investigator regarding all submitted and/or active protocols will be copied to the Administrative Investigator.

4. In specific instances where the WOC investigator had been a long-standing member of the GLA research community with full Principal Investigator status prior to assuming a WOC appointment, or has had a track record of participating in the VA Research in good standing, the WOC investigator may petition to be granted Principal Investigator status. This process can be initiated by memo to the ACOS, Research & Development who will recommend such action(s) to the Research & Development Committee for final approval.

**How to Become a HSR&D Principal Investigator**

1. The VA Greater Los Angeles Healthcare System (GLA) has developed a HSR&D Advisory Group to review, discuss and vote on requests for the prospective HSR&D PI status. The Advisory Group meets on a monthly basis to review such requests, in addition to overseeing short and long-term career development and advancement of the local VA health services research workforce.

2. A Principal Investigator (PI) is the qualified individual who leads the conduct of a research study. The PI is responsible for all research activity taking place at the investigative site and is supported by ancillary staff to help move along the progress of the study.

3. To be considered for HSR&D PI status prospective PIs must submit a CV, a write-up/summary of research interests and a letter (for clinicians) from their Service Chief about the amount of protected time they are allotted for research.

4. The HSR&D Advisory Group convenes to accept or reject requests. Following negative decisions, Dr. Dean Yamaguchi, the Associate Chief of Staff (ACOS) for Research at GLA, is given a memo summarizing the rationale for the decision to the prospective PI. Following positive decisions, the Advisory Group gives Dr. Yamaguchi their recommendation for HSR&D PI status. Dr. Yamaguchi then notifies the PI of the decision and informs the R&D Committee of the new HSR&D PI status.

[http://vaww.portal.gla.med.va.gov/sites/Research/csh/Pages/ab.aspx](http://vaww.portal.gla.med.va.gov/sites/Research/csh/Pages/ab.aspx)
OBLIGATIONS OF VA RESEARCH INVESTIGATORS

The following “GOLDEN RULES” must be adhered to by all VA Principal Investigators (includes part-time VA FTEE and WOC Investigators performing research at the VA). The performance of research at the VA is a privilege, and not a right, bestowed upon clinicians and non-clinicians at the VA who wish to conduct research.

1. Safety in the research environment which includes patients enrolled in research protocols and the employees performing the research is of the highest concern. Vigilance in the compliance of assurances for research subject safety and employee safety and health in the work environment must be highly profiled. Completion of the initial training of new research employees which occurs in concert with Research Service and the Principal Investigator must be accomplished; these courses include VA ORD Biosecurity Course, Information Security 201 for Researchers, VHA Privacy and Information Security Awareness course for ALL research employees and appropriate Human Subjects Protection and Good Clinical Practices course for those involved in human studies and/or Working with the VA IACUC, species specific training, and other appropriate training courses for those involved in animal studies. Completion of the initial and annual safety refresher course and the laboratory hazard communication and hazardous waste course is required for all employees conducting basic, animal, and/or human studies with blood borne pathogen exposure. Principal Investigators are responsible for the correction and response to the annual laboratory inspections and any safety hazards that may be potentially harmful in the research environment. ALL research employees working in a “wet” laboratory and/or involved in animal research will need to be enrolled in the Occupational Health and Safety (OHS) Program. Employees may opt out of the OHS Program by submitting a written and signed request to opt out. The request should be sent to Research Human Resources Section.

2. All employees engaged in research must have an appropriate appointment at the VA. This can be a VA-paid position or a Without Compensation (WOC) appointment at the VA. Employees can only begin to work on a research project when all their research credentialing requirements have been met. This includes, but not limited to, a valid VA appointment, completed a background check, education above high school verified, all licenses verified, have completed the above training, and have a Scope of Practice. Employees must wear their VA ID badge and the badge must be visible while working in Research buildings.

3. A hostile work environment will not be tolerated and reporting of hostile incidents including discrimination and sexual harassment should be reported to the employee’s immediate supervisor and to the Research Office. Additional information on the Equal Employment Opportunity (EEO) office at GLA may be obtained from the EEO Office (310-478-3711 ext. 43146).

4. All research projects (even pilot-type projects or those “without funding”) must have approval for the work to be initiated at the VA. Additionally, approval is required for VA Investigators who use their VA time when conducting their research at a non-VA site, or enrolls VA patients into the projects or protocols at the VA. Thus, all research projects must be submitted for appropriate review to the Research & Development Committee or its subcommittees through the Investigator Service Center (building 114, room 130). When VA resources are used to support the Research (PI’s VA time, time of other VA employees, VA space, equipment, etc), the VA is “engaged” in the research and thus the research must be reviewed and approved by a research committee at the VA. The research project can only begin once the PI is given written notification from the Office of the ACOS, Research that the project can commence.

5. All publications emanating from a VA Investigator must acknowledge VA sources of funding and VA affiliation. Any work done at the VA by part-time VA employees and WOC employees must also acknowledge VA funding sources and VA affiliation. VA employees who have 5/8 or more VA FTEE must list the VA as the first institution on a publication if that publication is done with any VA resources.
6. The Research and Development Information System (RDIS) requires annual Project Summaries to be completed on all approved VA projects. Approved VA projects are those projects granted final approval for performance by the Research & Development Committee or appropriate subcommittee (e.g. IRB, IACUC, and Subcommittee for Research Safety). These summaries must be completed in a timely fashion and in the required format specified. These summaries become public information and may be used as reports for VAHQ Research Office use or Congressional information.

7. The RDIS also requires that towards the end of each VA fiscal year (October 1-September 30), each VA Investigator completes information on amounts expended on VA and non-VA grants on the RDIS Expenditure Report. The local Research Office will fill in the VA expenditure portion but the Investigator is responsible for accurate reporting of all non-VA grant expenditures. If the funded projects are administered by the VA Non-Profit Corporations, expenditures on these projects are forwarded by the VA Non-Profit Corporations to the Research Office. However, should projects be administered by the University Affiliate or the RAND Corporation, expenditures on any such NIH grants, sponsored research, and foundation grants must be provided by the Principal Investigator to the Research Office. This information is crucial for the funding of Research through the Veterans Equitable Resource Allocations (VERA) formula where funds generated by research grants and contracts can come back to GLA by a VERA resource formula.

8. Research Investigators should reconcile their own budget records with the budget reports provided by Research Service to ensure that there is adequate cross-check on allocations and expenditures.

9. All Research Investigators have an obligation to participate in the governance of Research Service by giving community service to Research Service in the form of serving on the Research & Development Committee and/or its subcommittees. The Academic Chairs of each Department or Service will be responsible for ensuring that faculty who conduct research serve on such committees or are granted time to serve on a Research Committee, but it is the appointed Investigator who must fully participate by virtue of consistent attendance and genuine involvement in the workings of the committees.

10. Deadlines for grant submission and the submission of all required reports must be adhered to. VA grants that are not submitted for review by the website posted deadlines to Research Service will not be accepted for review.

11. All newsworthy research findings and events should be reported to the Associate Chief of Staff, Research & Development in advance of anticipated local, national, or international publicity. In this manner, the Research Office will be able to alert the Public Affairs Office at GLA and VACO as necessary.
Memorandum

Date: December 31, 2017
From: Associate Chief of Staff, Research & Development
Subj: Research Community Service
To: All Investigators

1. In a previous memo from September, 2000, community service to the research mission at the VA is an extremely crucial endeavor that allows for research governance. It is again stressed that faculty with full-time, part-time VA FTEE, or WOC investigators whose primary research site is at the VA, or who enroll Veteran patients into research protocols participate in research community service on a rotating basis.

2. Senior level investigators (clinician investigators and research PhDs) are expected to serve on formal research service standing committees and/or ad hoc groups delegated to make recommendations to the Research & Development Committee and/or the ACOS, Research & Development on a variety of issues relative to Research Service for the successful operation of research at GLA.

3. The ACOS, Research & Development and Chief of Staff will solicit faculty based on expertise needed for community service through the Academic Chairs. It is suggested that the Academic Chairs will set up a rotation amongst the senior faculty in their respective Departments for community service. Should an appointed faculty member not be able to participate in the assigned service or that attendance and/or participation for the service obligation is less than satisfactory, the Academic Chair will be responsible to resolve the situation.

4. When faculty members appointed for research community service do not participate or participation is less than satisfactory based on attendance and/or quality of service provided, and the situation cannot be resolved by the Academic Chair, such faculty members may lose the privilege having their protocols reviewed by the subcommittees of the Research & Development Committee and/or have their Principal Investigator status put on probation or revoked.

//es//
Dean T. Yamaguchi, M.D., Ph.D.
There have been many changes in Research Administration over the course of the last several years. We are aware that Investigators receive an avalanche of notices about projects and personnel that seem redundant and confusing. As much as we try to keep people abreast of current changes and upcoming issues, we continue to struggle with the ever-changing requirements to keep up with the administrative workload. Below is a summary of the current requirements for maintaining compliance with the various aspects of research oversight. As much as possible, we utilize notification systems to remind Investigators and staff as to renewal, training, and continuation requirements, however, *it is every Investigator's responsibility to ensure that all requirements are met in a timely manner*. In order to ensure that Investigators receive information from the Research Service in a timely and expeditious manner, it is incumbent on investigators to update Research Service of current e-mail addresses (multiple e-mail addresses, both VA and non-VA will also be accepted although VA business through e-mail should be conducted using a VA e-mail address (Outlook), phone numbers (cell phones are welcome), and/or FAX numbers. Investigators should as common practice pass information on to all members of their research team as having as many informed research staff as possible lessens the likelihood that an important matter (e.g. project continuation reviews, staff reappointments, training requirements, etc) does not “fall through the cracks” because “I didn’t know this or was not informed to do this.”

Requirements are governed by Regulations, Laws, Directives, Handbooks, Information Letters, Policies, and other communications that we receive from a variety of sources. The policy documents and handbooks that are most relevant to research can be found on the R&D website at: [http://www.research.va.gov](http://www.research.va.gov) on the internet. Research funding opportunities are only available at: [http://vaww.research.va.gov](http://vaww.research.va.gov) (intranet). Additionally, the VA RFAs applications can only be downloaded via the VA Intranet on grants.gov.

If you have suggestions for improvement in any process, please familiarize yourself with the governing requirements. We are always looking for ideas to make things better, but ignoring or doing away with the regulations does not work very well.

**General**

For VA funded projects: If the project is approved for funding, the funds will not get released until all relevant subcommittees have approved the project. It is important that this is completed as quickly as possible. (Contact: Sharon Saivar, DPA, Head of Investigator Services).

VA funds are awarded on a two-year cycle. That is: funds awarded in Fiscal Year 2016 can be spent in FY16 and FY17. This does not mean that one can carry forward large sums from one year to another. In fact, we are limited to carrying forward unobligated funds to 1-2% of the awarded dollars, depending on the year. We can usually accommodate carryover funds under special circumstances, but this is not a guarantee that all funds will be carried forward, depending on the overall fiscal status of the program. PIs that need to preserve funds across the fiscal year line must have a plan for expenditure and the plan must be approved by the Administrative Officer as early as possible. Those who wait until the last-minute risk losing at least some of the funds awarded.
All projects that are not funded by the VA (i.e. Research Appropriation) where greater than 50% of the work (not the budget but physical location of where the work is done) will be done at GLA must be administered by one of the VA non-profit corporations (NPC), the Brentwood Biomedical Research Corporation (BBRI) or the Sepulveda Research Corporation (SRC). If there is some compelling reason that the non-VA funded grant needs to be administered at one of the affiliate universities, a waiver request must be submitted to the R&D Committee through the NPC, the ACOS, the COS, and the Director. The reason for this is that GLA receives no indirect support from the universities, and this support is essential for support of the program. Please note that only the NPCs may be used and any other non-profit foundation (e.g. Friends) may not be used as a source of research funds administration when greater than 50% of the work is performed at GLA.

All studies are required to have an annual update. This is a VA Central Office requirement. Notification is sent from the Investigator Services Center. The notice is accompanied by a “Project Data Sheet” (PDS), and a copy of the initial and any other progress reports submitted by the PI. What we are interested in is progress, i.e., publications or presentations that have been completed in the previous year, enrollment, preliminary data, etc. This is separate and apart from continuation reviews, although the data may be used as part of the continuation evaluation. The PDS and progress reports are due on the anniversary of the initialization of a project.

**Personnel**

With few exceptions, all personnel appointments must be renewed every two years. This includes VA Term appointments, WOC appointments, and IPA appointments. Whereas VA and WOC appointments are done on an annual basis, typically by anniversary date of the initial appointment, IPA appointments are done by fiscal year, regardless of the initial contract date. VA Term appointments have a maximum life of 4 years, after which, the position must be re-competed.

Some requirements such as Research Credentialing and an initial Scope of Practice for those involved with Research are processed by Research Personnel Section. Credentialing for those persons that have licensure to providing clinical services are processed through HR (for dependent providers) or by the medical center’s Credentialing and Privileging Office (for independent providers). The system that tracks these persons is called VetPro, and processing through VetPro is currently the most restrictive bottleneck that prolongs WOC appointment.

**Appointments:** VA Term: One year and WOC: Every two years.
**IPAs:** Once per fiscal year - no notices.
**Research Credentialing:** One time only unless employee status changes (i.e., duties are added)
**Scope of Practice:** one per employee per investigator; does not expire unless there have been additional duties assigned to the employee, then a new SOP must be sent to ACOS.

**Training**

Training requirements are dependent on the type of study to be done. All personnel are required to keep training current. The training calendar is kept by fiscal year, so each year all training must be completed by September 30. The exception to this rule, are trainings that are also required for the Medical Center (“VHA Privacy, Information Security and Rules of Behavior”, “VA Privacy and HIPPA” and “Government Ethics – The Essentials”) must be completed by their anniversary date. The listing of required training for all research staff and for those involved in specific types of research is located in the training section of this manual.
Human Studies

Human Studies are the most regulated cadre of studies in any institution’s research portfolio. Human subject research is overseen by the Human Research Protection Program (HRPP). The primary mission of this program is the protection of human subjects in research, and the vehicle of review is the Institutional Review Board (IRB). Following the initial review, all studies must have a thorough continuation review on an annual basis. Initial notification for continuations are sent out approximately 3 months prior to the expiration date of a study, which is the anniversary date of the convened IRB meeting where the study was initially approved-pending or fully approved. The reason for this is that the notification begins 2 weeks prior to the cutoff date for the penultimate meeting at which the project needs to be reviewed prior to expiration. Additional notifications are triggered by the submission, or lack or submission, of the continuation application as other cut off dates pass. Should a study not be approved prior to the end of the previous approval period, work on the project must cease and IRB guidance obtained as to the disposition of currently enrolled patients. In order to reinstitute the study, a new submission for IRB and SRS review is necessary.

In addition, there is a requirement for submission of all unexpected local and related, and all serious non-local and related Adverse Events. Appointment status and training for all employees working on studies must be kept current. All modifications to the protocol are investigator initiated unless required by the IRB or policy change.

All continuations (unless the study is exempt from Subcommittee for Research Safety (SRS) review) and modifications of IRB applications must also be seen by the SRS). Also, all Human Subjects projects must be accompanied by a Data Use and Security Plan (DUSP), which are reviewed by the Information Security Officer and Privacy Officer. DUSPs need only be reviewed once, unless something about the study changes, or there is a change in policy, that would require a change in the DUSP.

IRB continuations: Annually based on the date of the convened IRB meeting at which the project is at least “approved, pending minor changes” or fully approved. Sign off by the chair and project initialization is dependent on satisfaction of any changes mandated by the IRB.

Animal Studies

Animal studies are overseen by the Institutional Animal Care and Use Committee (IACUC). The primary charge of this committee is to govern the humane use of animals in research. All projects require a veterinary consultation prior to submission. Animal studies are reviewed on the anniversary of the final sign-off date for approval. Animal continuations for the two years require a completion a simple form. If a project continues for three years or more, a triennial review is required that is essentially a full review of the protocol de novo. An integral part of the animal studies program is the Veterinary Medical Unit (VMU), which is responsible for the husbandry aspects of the program. Projects submitted to the IACUC are also reviewed by the Subcommittee for Research Safety (SRS). Likewise, all continuations and modifications are also reviewed by the SRS. The courtesy notification system uses a similar algorithm to the human subjects projects. Should a study not be approved prior to the end of the previous approval period, work on the project must cease and IACUC and VMO guidance obtained as to the disposition of currently enrolled animal subjects. In order to reinstitute the study, a new submission for IACUC and SRS review is necessary.

IACUC Continuations: Once per year based on the date when the project is signed off by the chair. Triennial reviews are based on the same anniversary date, but follow by 3 years after the initial approval.
Subcommittee on Research Safety

The Subcommittee on Research Safety (SRS) has responsibility for protection of employees in a research setting. Aside from the usual laboratory environments, they are also responsible for oversight of sample storage and transport that potentially might present an exposure hazard to those in non-laboratory situations. The SRS must review all new studies and all modifications to studies to determine if these hazards exist. If a study is not primarily overseen by IRB or IACUC, and potential hazards to employees exist, then the SRS becomes the primary subcommittee of record for these studies and is responsible for annual continuation review.

The SRS review consists primarily of two components: 1) Annual review of the PI's research program. This involves a combination of a Laboratory Safety Plan (LSP), in concert with an on-site review of the PI's space by the SRS, and 2) Review of new protocols annually and review of all modifications to protocols. Protocol review takes place on the anniversary date that the SRS chair signs off on a protocol. Should a study not be approved prior to the end of the previous approval period, work on the project must cease. In order to reinstitute the study, a new submission for SRS review is necessary.
SUBMISSION OF RESEARCH PROTOCOL FOR REVIEW

All Forms necessary to initiate the review process for submitted protocols can be obtained from the ISC Office or the subcommittee coordinators. Additionally, All IRB Forms: http://vaww.portal.gla.med.va.gov/sites/HRPP/Forms/Forms/AllItems.aspx

1. The following, plus committee specific forms, must be submitted through the Investigator Service Center (bldg. 114, room 130) or Research Office (bldg 1, room C111a):
   - All new research proposals, modifications/amendments, continuations, etc.
   - All revisions requested by a subcommittee of the Research & Development Committee (IRB, IACUC, Safety and all Adverse Events, etc.).

   New proposals and modifications that change the PI time commitment must be signed by the Principal Investigator and, as necessary, the Service Chief of the Service or Department to which the Principal Investigator belongs. A cover memo detailing the submission, modification, etc. is highly recommended.

The Investigator Service Center serves as the clearinghouse for all research proposals. A computerized tracking system is in place to help Research Administration and the Principal Investigator know where each protocol stands in the approval process.

All submissions must be entered into the ISC log in building 114, room 130 at the WLA Campus. Alternately, submissions can be entered into the Research Committee and Compliance log in building 1, room C111a at the Sepulveda Campus.

2. The Request to Review Research Proposal/Project application should be completed for any new submission. It is imperative that the Service Chief of the Principal Investigator approve the submission of any protocol. Protocols submitted to the Investigator Service Center without Service Chief’s approval will be returned to the Principal Investigator. Additionally, any research project administered by the Non-Profit (BBRI or SRC) must have the Non-Profit approval before submitting the project to ISC.

Please Note: For Principal Investigators who have not previously submitted a protocol through the Investigator Service Center must have been given PI status by the ACOS for Research before submitting a protocol. Once you receive PI status you will not show up as a Principal Investigator in our data base until you submit a research project. This also means that we cannot research credential your staff until we can attach them to a research project.
## Dates and Location of Meetings of Research & Development Committee and Subcommittees

<table>
<thead>
<tr>
<th>MEETING</th>
<th>DATE</th>
<th>TIME</th>
<th>LOCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research &amp; Development Committee</td>
<td>Last Wednesday of each month</td>
<td>12 PM</td>
<td>West L.A., bldg. 114, room 125 Sepulveda via V-Tel, bldg. 1, room B125.</td>
</tr>
<tr>
<td>IRB-A</td>
<td>1st Tuesday of each month</td>
<td>1:00 PM</td>
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<tr>
<td>IRB-B</td>
<td>3rd Wednesday of each month</td>
<td>1:00 PM</td>
<td>West L.A., bldg. 114, room 125</td>
</tr>
<tr>
<td>IRB-C</td>
<td>No Specific Date, Reviews Expedited Reviews</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IACUC</td>
<td>1st Wednesday of each month</td>
<td>1:00 PM</td>
<td>West L.A., bldg. 114, room 125 Sepulveda via V-Tel, bldg. 1, room B125.</td>
</tr>
<tr>
<td>Biosafety Subcommittee</td>
<td>3rd Wednesday of each month</td>
<td>1:00 PM</td>
<td>West L.A., bldg. 114, room 125</td>
</tr>
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4. A research protocol may commence only when final approval from the Research & Development Committee is granted, the investigator has notified ISC to activate the study, and final approval is communicated to the Principal Investigator via memo from the ACOS for Research & Development.
SUBCOMMITTEE FOR RESEARCH SAFETY (SRS)

The SRS is responsible for the safety of personnel. The safety of research subjects is the responsibility of the Institutional Review Boards (IRBs). The SRS is directly responsible for safety and security in research areas only. Issues relating to safety and biohazards encountered in clinical and other non-research areas are the responsibility of the Environment of Care, Hospital Infection Control, and/or other Medical Center committees.

As a subcommittee of the Research and Development Committee, the SRS's responsibilities include:

1. Establishing policies and procedures regarding the security of research areas, and the safety of all personnel working or visiting those areas.
2. Reviewing all proposed activities involving biological, chemical, and/or physical hazards in research areas for compliance with all applicable regulations, policies, and guidelines.
3. Reviewing, at least annually, all active research protocols involving biological, chemical, and/or physical hazards in research areas. Also, reviewing all proposed modifications to active research protocols involving these hazards before the changes take place.
4. Evaluating biocontainment levels, personal protective equipment (PPE), health surveillance measures, training, operating procedures, and other measures necessary to ensure the safe of those working with, or coming in contact with, potential hazards in research areas.
5. Ensuring the proper reporting of injury and illness trends, and requesting, when appropriate, the appointment of an ad hoc committee (consisting of members with appropriate expertise) to investigate and report on occupational injuries, illnesses, and adverse environmental events related to the research program.
6. Coordinating the review and oversight of hazardous chemicals and the chemical hygiene program by the GLA Safety Office, and the review and oversight of radiation hazards by the GLA Radiation Safety Committee.
7. Coordinating all safety-related activities in research laboratories including appropriate training, safety inspections, accident reporting, and liaison activities with all facility safety committees and officials.
8. Establishing security measures necessary to protect research areas from unauthorized access, and to prevent unauthorized removal of hazards from research areas.
9. Evaluating and reporting any serious violations of safety or security procedures to all relevant authorities.
10. Developing and evaluating disaster, emergency, and evacuation plans for research areas.

SAFETY IS MY RESPONSIBILITY
Human Subject Studies

Institutional Review Board

All activities related to human subject research, regardless of funding source, will be guided by the ethical principles of respect for persons, beneficence and justice as articulated in the Belmont Report. 151-HRP-02 May, 2010.

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their staff, the subjects who enroll in the research, and the Institutional Review Board (IRB) members and staff. The responsibilities of the IRBs are to determine if: 1) the PI has access to a population that would allow recruitment of the necessary number of participants; 2) the PI will have sufficient time to conduct and complete the study safely; 3) the PI has an adequate plan to train everyone on his/her research team about the protocol and their research-related duties; and 4) the institution has medical, psychological services, or other services necessary, to protect research subjects are available for participants who might need them as a consequence of the research.

GLA does not conduct fetal or human in vitro fertilization research, human fetal tissue transplantation research nor research on pregnant women. It is extremely rare that this institution is involved in research involving children and that only occurs with the approval of VA Headquarters and only involves testing of biological samples that have been obtained elsewhere under the auspices of an IRB properly constituted to review pediatric research. Prisoner research is only reviewed by one IRB which has been constituted to conduct review of prisoner research. GLA does not conduct emergency research.

VA research focuses on Veterans as subjects. However, VA regulations do allow non-Veterans to enroll in VA-approved research studies when there are insufficient Veterans available to complete the study and diversity and equitable selection of subjects require a larger subject pool. This may include adults with no decision-making impairment as well as adults with decision making impairment (if specifically approved by the IRB). It may also include students and trainees. Research is conducted at all areas of GLA identified in the GLA’s FWA. In addition, GLA has a large Health Services Center of Excellence which serves as a coordinating center for multi-site health delivery evaluation studies which involve large numbers of VA facilities.

All regulations pertaining to the participation of Veterans as research subjects including requirements for indemnification in case of research-related injury, also pertain to non-Veteran subjects enrolled in VA approved research. A VA medical record must normally be created for each subject for whom a consent waiver has not been granted, although in specific instances where participant privacy and release of information to construct a VA medical record would unduly constitute greater risk than study participation itself, the requirement for a VA medical record is governed by VHA Handbook 1907. Subject to the provisions of 38 CFR 17.62 and 38 CFR 17.101 any person who is a bona fide research volunteer may be admitted to or furnished outpatient treatment at GLA when the treatment to be rendered is part of an approved VA GLA research project.
VA GREATER LOS ANGELES- HUMAN SUBJECT RESEARCH INVESTIGATOR GUIDANCE*

OBTAINING IRB APPROVAL – THE REVIEW PROCESS

The four different regulatory classifications that research activities may fall under

- **Not “Human Research”:** Activities must meet the DHHS or FDA definition of “research” involving “human subjects” for the activity to fall under IRB oversight. Activities that meet neither definition of “Research involving “Human Subjects” are not subject to IRB oversight or review.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the IRB, not the investigator, to determine whether Human Research is exempt from IRB review.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt Human Research may qualify for review using the expedited procedure

- **Review by the Convened IRB:** Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

**Required forms for non-human research include:**

1) Request to Review  
2) Biosafety – SRS Forms – Waiver or Full Application  
3) Staffing List + Statement of Disclosure (regarding Conflict of Interest) for EACH staff member on the staffing list  
4) ANY other forms required by LEAD subcommittee (SRS or IACUC)  
5) Form 00 (and any specific requests from HRPP Administrator/ IRB Coordinator – such as verification from providing physician about de-identified data, specimens)  
6) Financial Conflict of Interest Statement (Alt-450)

**Additional requirements:** Stand Alone Protocol, grant (if applicable)

**THE PROCESS:** IRB MEMO with non-human research determination with Chair sign off; SRS – or Biosafety Review and REQUIREMENT FOR FULL RDC REVIEW

**Required forms for Human Research include:**

1) Request to Review  
2) Biosafety Form: Subcommittee for Research Safety (SRS)  
3) Personnel Forms: Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for all co-investigators and consultants, and  
4) ANY other forms required by LEAD subcommittee (SRS or IACUC)  
5) Form 00 (and any specific requests from HRPP Administrator/ IRB Coordinator – such as verification from providing physician that data and/or specimens are de-identified to the receiving researcher)

**Additional requirements:** Stand Alone Protocol, grant (if applicable)

* Please see Appendix B for additional and more in-depth IRB information.
THE PROCESS:

- Any application deemed to be research, that is not human research, will receive a signed Form 00 (by the HRPP Administrator or Expedited IRB reviewer) with the determination and an email. In complicated cases where there are restrictions and/or future human research is planned, a memo may be provided, if required by a funding/external institution or other entity.

- The main subcommittee (Subcommittee or the R&D) will be the holder of the file.

- Per VHA requirements, the research must be overseen if the research is VA Research.

A. RESEARCH FORMS THAT ARE REQUIRED EXEMPT HUMAN SUBJECT RESEARCH AND THE PROCESS

Required forms include:

1) R&D Form: Request to Review
2) Biosafety Form: Biosafety – Subcommittee on Research Safety (SRS) Form
3) Personnel Forms: Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for each investigator and consultant on the project
4) ANY other forms required by LEAD subcommittee (SRS or IACUC)
5) IRB Form 1 - with exempt criteria and justification completed in the Form 1.
6) Additional requirements: Stand Alone Protocol, grant (if applicable)
7) Stand Alone Protocol, grant (if applicable)

THE PROCESS: Any application deemed to be EXEMPT will receive a single IRB determination by an IRB Administrator or IRB member. A memo of IRB exemption will be provided to the PI and to R&D and shared with any other subcommittee, who needs to be informed of the IRB determination. The main subcommittee or R&D will be the holder of the file.

An EXEMPT determination is good for the life of a study, unless the study is modified. However, all MODIFICATIONS to IRB EXEMPT projects require re-review by the IRB to determine if the EXEMPT status still holds.

Annually, the investigator must submit a continuation form to R&D and receive continuing review and R&D approval.

B. HUMAN SUBJECT (NON-EXEMPT) RESEARCH FORMS AND THE PROCESS

Required forms include:

1) R&D Form: Request to Review
2) Biosafety Form: Biosafety – Subcommittee for Research Safety (SRS) Form
3) Personnel Forms: Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for investigators and collaborators
4) IRB Form 1, AND
5) Any materials required – consents, HIPAA and any other necessary materials for advertising or scripts (any materials necessary for interacting with subjects)
6) Additional requirements: Stand Alone Protocol, grant (if applicable)

THE PROCESS: All applications are given a pre-IRB meeting review to triage review process – expedited review or review by the fully convened IRB.
**Triage Process:** All expeditable applications are either approved by the Chair or expedited reviewer or forwarded to the fully convened IRB, if the study cannot be expedited. No study can be disapproved by the Chair or expedited reviewer.

The fully convened IRB then reviews the IRB application, protocol and miscellaneous documents and determines whether the study may be approved, require changes to achieve an approval, tabled or disapproved. The PI will receive a memo with the determination and findings of the IRB and instructions regarding any modifications necessary to achieve an approval, if the study is not approved without contingencies or conditions.

I. **IRB DETERMINATIONS - REVIEWED BY THE FULLY CONVENED IRB**

The IRB may approve research, require modifications to the research to secure approval, table research, defer it or disapprove research:

- **Approval:** Made when all criteria for approval are met. See “How does the IRB decide whether to approve Human Research?”
- **Approved Pending (minor contingencies):** Made when all criteria for approval are met, but minor changes are necessary to achieve a final approval. These minor changes are typically simple changes to documents.
- **Modifications Required to Secure Approval (or approved with conditions):** Made when IRB members require specific modifications to the research before approval can be finalized. This determination indicates that IRB approval criteria are met, however, certain conditions or documents are necessary, requiring review by the Chair and/or a primary reviewer is needed to verify that the modifications ensure that the study meets IRB approval criteria.
- **Deferred:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.
- **Deferred/Tabled:** Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- **Disapproval:** Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.
II. INVESTIGATOR RESPONSIBILITIES AFTER IRB APPROVAL

A. PI OBLIGATIONS AFTER IRB APPROVAL

1) Do not start Human Research activities until you have the final IRB approval letter and have met all contingencies and conditions of that approval letter.

2) Do not start Human Research activities until you have the approval of departments or divisions that require approval prior to commencing research that involves their resources.

3) Do not start Human Research activities until you have received the notification of the ACOS for Research. This notification indicates that all necessary approvals from all entities are in place for the study to begin.

4) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

5) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.
6) Personally conduct or supervise the Human Research.
   a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB.
   b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
   d) Protect the rights, safety, and welfare of subjects involved in the research.
7) Submit to the IRB:
   a) Proposed modifications as described in this manual. (See “How do I submit a modification?”)
   b) A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”)
   c) A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)
8) Report the any of the information items to the IRB within five business days.
9) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
10) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
11) See additional requirements of various federal agencies

B. MODIFICATION SUBMISSION

• Complete the Form 6 - attach all requested supplements (including updated Form 1, updated consents, protocols, materials, such as scripts, etc.)
• Provide the requested number of copies to the Investigator Services Center (ISC)
• Maintain electronic copies/paper copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received.
• NOTE: A modification, which requires IRB review may be implemented after IRB approval only, unless other entities are necessary as part of the review process. For example – if a new HIPAA is required, the Privacy Officer has to endorse this, prior to use.

C. CONTINUING REVIEW SUBMISSIONS

• Complete the IRB Form 3 – the Continuation Application –
• Sign the form, and provide any necessary attachments with any necessary signatures as well as the requested number of copies (3 copies) to the ISC Office.
• Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications as a separate request for modification using the Modification Form.
If the approval of Human Research expires, all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of federal regulations. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB coordinator and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.
D. FINALIZATION OF RESEARCH PROJECT
Complete the “IRB Form 7,” sign the form and include any necessary attachments and provide the requested number of copies (2) to the ISC Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

In addition to closing a study, at VA, investigators have additional responsibilities regarding accounting for disclosures and record retention in compliance with the Record Control Schedule.

E. UNUSUAL SITUATIONS – EMERGENCY USE AND THE IRB

USE OF AN UNAPPROVED DRUG OR DEVICE IN A LIFE-THREATENING SITUATION WITH NO TIME FOR PRIOR IRB REVIEW
Contact the IRB Office – the HRPP Administrator or an IRB Chair. If there is no time to make this contact, see the EMERGENCY USE CHECKLIST/EXPANDED USE ACCESS (EMERGENCY USE SECTION) for the regulatory criteria allowing such a use and make sure these are followed. You will need to submit a report of the use to the IRB within five days of the use and an IRB application for initial review within 30 days.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is “research” as defined by FDA, the individual getting the test article is a “subject” as defined by FDA, and therefore is governed by FDA regulations for IRB review and informed consent. Emergency use of an unapproved device in a life-threatening situation without prior IRB review is not “research” as defined by FDA and the individual getting the test article is not a “subject” as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic. Individuals getting an unapproved drug or device in a life-threatening situation without prior IRB review cannot be considered a “subject” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS.

A. POST APPROVAL – REQUIRED PROMPT REPORTING TO IRB

• Follow this organization’s procedures to ensure reporting in writing to the IRB within 5 business days of becoming aware of:
  
  • unanticipated problems involving risks to subjects or others,
  
  • apparent serious or continuing non-compliance,
  
  • suspension of IRB approval, termination of IRB approval, and local (i.e., occurring in the reporting individual’s own VA facility)
  
  • unanticipated serious adverse events in writing to the IRB within five business day.

• This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements.) The unfounded classification of a serious adverse event as “anticipated” constitutes serious non-compliance.

• It is the policy of GLA that:
  
  • In addition to the requirements for continuing review and submitting protocol amendments, the Principal Investigator must submit to the IRB all post approval reports as defined in this SOP.
  
  • The investigator is responsible for reporting events that are unanticipated problems, serious adverse events, and new information, which meet post-approval reporting criteria within specified time frames.
• After reviewing these reports, the IRB must determine the adequacy of the safeguards in place and make appropriate determinations regarding risks, potential benefits, the adequacy of the consent documents, the provision of updated information to subjects, and the safeguards that are in place to protect human subjects, including subject privacy and the confidentiality of data.

• The Principal Investigator must make any changes to the protocol or recruitment or consent documents as required by the IRB.

• The Principal Investigator is responsible for submitting to the IRB ongoing reports of events that are unanticipated problems, and information regarding the conduct of the approved research. The expertise of the investigator is relied upon to make an initial assessment and determine the relationship of the event to the research activity and to determine if the event warrants a change to the protocol to minimize risks to human subjects and/or a change to the informed consent form to better inform subjects of the potential risks and the procedures needed to minimize such risks.

• Not all adverse events, violations, incidents or deviations are unanticipated problems. Examples are provided below of the types of events that do constitute unanticipated problems and, therefore, must be reported. There are also examples of events that need to be reported whether or not they are unanticipated problems.

**B. ROUTINE REQUIREMENTS OF VA INVESTIGATORS**

• The principal investigator, local site investigator, and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the local VA facility’s SOPs, regarding the conduct of research and the protection of human subjects.

• The responsibilities of the investigator may be defined in the protocol or IRB application. Specifically, the principal investigator’s and local site investigator’s responsibilities include, but are not limited to
  • **Disclosing Conflicts of Interests.** This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.
  • **Ensuring Adequate Resources.** This means ensuring there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
  • **Ensuring Qualified Research Staff.** This means ensuring research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study. In a protocol, study team members are generally identified by name or by title.

**C. PERSONNEL IN VA RESEARCH – CHANGES DURING A STUDY OVERSIGHT – APPOINTMENTS**

• If a study team member is identified by name in the IRB-approved protocol, a replacement or termination of their role constitutes a change in the protocol. Such a change requires IRB approval (e.g., if an IRB-approved protocol specifically identified the name of a medical monitor and later another individual was identified to replace the medical monitor, the protocol would require an amendment reflecting the change in the name of the medical monitor. This protocol change would require IRB approval prior to initiation of the change, unless it was necessary to eliminate apparent immediate hazards to the subjects).
If a study team member is replaced by another individual and the IRB-approved protocol identifies the person by title and not name, a replacement by another individual with the same title is not a protocol change.

No IRB approval is required (e.g., if a principal investigator appointed a new research study coordinator to replace the original research study coordinator in an IRB-approved protocol when neither is mentioned by name, the replacement in personnel does not require approval by IRB because the protocol remains unchanged).

IRB may also require a specific individual(s) by name to be part of the study team as a condition for IRB approval of the research. In that case, a proposed change in that specific individual would require IRB approval.

**NOTE- PI changes must be prompt: Promptly Reporting Changes** in principal investigator or local site investigator. This means promptly reporting any changes in the principal investigator or local site investigator to the IRB. Changes in other key research staff, if any, must be reported at time of continuing review, or sooner as required by local SOPs. These changes include, but are not limited to, additions to or loss of staff. Changes in the principal investigator, local site investigator, Co-principal investigator, or Co-local site investigator of an IRB-approved project must be evaluated and approved by IRB to ensure the new individual meets the criteria described in 38 CFR §16.111.

**D. LAST DETAILS - STARTING A STUDY AT GLA – ENSURING COMPLIANCE TO PROTOCOL & VA REQUIREMENTS**

- **Ensuring Complete Information in Research Protocol.** This means ensuring the research protocol contains all required information.

- **Obtaining Written Approvals.** This means obtaining written approval(s) before initiating research. Before initiating the research study at a given site, IRB approval must be obtained in writing from the Chair or other voting member of the IRB, and all other committees (e.g., R&D Committee), subcommittees, and other approvals according to applicable local, VA, and other Federal requirements.

  - **For a VA multi-site study,** not only the principal investigator, but also all local site investigators, must obtain such approvals from the relevant local VA facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other Federal requirements.

  - **Research cannot be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local ACOS for R&D.**

- **Implementing the Study as Approved.** This means ensuring the study is implemented as approved by the IRB and in accordance with other required approvals and with all applicable local, VA, and other Federal requirements including, when applicable, those for research involving investigational drugs or investigational devices.

- **Maintaining Investigator’s Research Records.** This means maintaining written documentation on file that the protocol is being implemented as approved by IRB and in accordance with other required approvals.
  - Retain research records until disposition instructions are approved by the National Archives and Records Administration and are published in VHA’s Records Control Schedule (RCS 10-1).
• Research records include the following when relevant to the study:
  ▪ Copies of all IRB-approved versions of the protocol and amendments.
  ▪ Case report forms and supporting data, including, but not limited to, signed and dated informed consent forms and HIPAA authorizations.
  ▪ Documentation on each subject including, but not limited to:
    • Informed consent,
    • Interactions with subjects by telephone or in person,
    • Observations,
    • Interventions, and
  ▪ Other data relevant to the research study, including, but not limited to:
    o Progress notes,
    o Research study forms,
    o Surveys, and
    o Questionnaires.
  ▪ Reports of adverse events.
  ▪ Data analyses.
  ▪ Reports including, but not limited to, abstracts and other publications.
  ▪ All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities including, but not limited to, IRB, R&D Committee, ORO, and FDA.
• Documents must be maintained so that they may be audited by the facility RCO or other entities according to applicable sponsor, local, VA and other Federal requirements, and
• An Accounting of Disclosure must be maintained for each and every disclosure of information from this study to a non-VA entity. NOTE: The facility Privacy Officer can assist in providing a mechanism to account for this disclosure.
**CRC Information**

There are a variety of services available through the Clinical Research Center (CRC). First and foremost, there are examination rooms which have computer stations, examination tables and/or beds, vital sign units (Blood pressure, temperature, etc) and ophthalmoscopes. Each examination room is set up to accommodate a variety of research related activities, from patient interviews and physical examinations to blood draws and the consent process. There is a master calendar that is used to reserve and examination room, which is on a first come, first serve basis. This is a collegial environment and most groups try to help each other if there is greater need than space. In terms of reservations, call or email Kim Panizzon (Kimberly.Panizzon@va.gov), or come by and add your request to the master calendar. If there is a problem with reservations, then you can speak with Ms. Panizzon and she will try to resolve any issues.

There is also a small clinical laboratory, which is used for processing samples. If you have not been cleared by Ms. Panizzon to use the laboratory, you must schedule an appointment with her to receive permission to use the laboratory. This is a one-time review, but is required when new staff have been added to a protocol or if it is a project that requires techniques that the coordinator or PI have not previously performed. Safety is the important aspect to this review and generally, Ms. Panizzon will want to go through the project requirements and have the staff demonstrate how they will be utilizing the equipment. If you are using the centrifuge, the tubes must be balanced and this will be one of the key aspects will be that the staff show that they are familiar with universal precautions and that they can use the equipment safely. Ms. Panizzon will provide a training certificate for the staff members that complete this process.

If there is a new project that will involve use of the CRC or other medical resources (i.e., clinical examination rooms), then the project needs to be reviewed and approved by Ms. Panizzon. In general, the review involves confirming that the needs of the project can be met in terms of the resources available through the CRC and medical center. This includes use of the CRC laboratory for processing samples, use of dry ice, shipping materials, etc., use of the ECG device, use of the minus 70 freezer for storage of samples and the types of rooms needed for the assessments of subjects for a project. If there are any special needs, then this would be the appropriate time to discuss this with Ms. Panizzon so that she can facilitate any unusual requests.

Another function of the CRC is training. There are opportunities for educational programs held within the CRC to review CPRS, flagging charts, SOAP notes, completion of Impact forms, clinical trial budget assistance, etc. There is one-on-one training or group training sessions available with Ms. Panizzon regarding the CPRS template notes for research and how to complete the proper documentation to meet FDA regulations. A newly instituted program is a monthly CRC training session, which will be listed on the posted CRC events calendar so that the staff will have ample time to sign up and attend various training sessions. Most of the training sessions will be held in the afternoons, when the CRC is generally less busy, but morning sessions can be scheduled as well. Currently, the primary training session is held the first Friday afternoon (2:00 pm to 4:00 pm) each month. Sign-up sheets are located at the CRC or you can call Ms. Panizzon to sign up for a session.
Impact Form – Clinical Research Center (CRC) Fees

The Impact Form is used to capture the costs incurred for non-standard of care services provided to Research participants. Non-standard of care is defined as services that are required specifically for the sponsored research project. The Impact Form serves as a billing system to accurately track and bill the Non-Profit Organizations and University Affiliates, for non-standard of care costs incurred when PIs use Medical Center services to conduct non-VA funded research. The goal is to reimburse Medical Center services for the services provided to investigators in support of their research.

The New Impact Form can be found by clicking here. Vice versa it also can be found by going to the r:/ drive and selecting the Impact Form folder. Please contact Jennifer Freedman, Jennifer.freedman@va.gov, Research Budget Office, for access to the Impact Form site. It may take up to 24 hours for the system to update regarding your access to this drive/folder. The password for entering the database at this time is Password.

The Impact Form must be submitted monthly for all human subject projects. All services must be listed separately by subject. The ID can be whatever you want except it cannot be the last four numbers of the subjects’ social security account number. If the subject is being seen specifically for the research project then a Clinical Research Center (CRC) charge must be included in the Impact Form regardless if seen in the CRC. If seen outside of the CRC, the Impact Form is checked CRC and “list other location.”

Charges for Project Submissions

Sponsored Studies:

- Initial Submission Fee – $1,500.00
- Substantial Modification – Sponsor Initiated or multiple modifications over 2: $500.00
- Continuation Review Fee – $500.00
- FHPP Fee – 10% of direct costs of contract.
- Pharmacy Set-up Fee – $1,500.00
- Pharmacy Annual Fee – $500.00
- CRC Charge – $25.00
- CRC – Deep Freeze Storage – Storage in -80 freezer for 1 week: $15.00 (Storage is free the first 3 days, charges start on the 4th day at 1 week intervals.)
- CRC – Dry Ice (10 pounds): $6.00
- CRC – Lab Draw: $25.00
- CRC – EKG: $25.00
- CRC – Lab Processing: $5.00
- CRC – Vitals: $25.00
Institutional Animal Care and Use Committee (IACUC)

All activities related to animal subject research, regardless of funding source, will be guided by the VA Handbook 1200.07 (Use of Animals in Research); the Guide to Care and Use of Laboratory Animals (most recent edition) and the Animal Welfare Act.

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their staff, and the Institutional Animal Care and Use Committee (IACUC) members and staff and Veterinary Medical Unit (VMU) and staff. The responsibilities of the IACUC are to: 1) Review and approve animal use protocols and modifications; 2) Inspect the vivarium and all labs that use animals twice a year; 3) Investigate instances of non-compliance with regards to animal welfare and research.

VA research focuses on health issues that affect Veterans, and animal research protocols must specify how the research will benefit Veterans.
VA GREATER LOS ANGELES- ANIMAL SUBJECT RESEARCH INVESTIGATOR GUIDANCE

Submitted activities may fall under **one** of the following **three** regulatory classifications:

- **Review by the Convened IACUC:** Most animal research protocols are reviewed by the convened IACUC, which normally meets on the first Wednesday of every month.

- **Designated Member Review (DMR):** A PI may request to use the DMR process in order to meet a grant submission deadline or if a protocol will fall out of compliance before the next convened IACUC meeting. If the IACUC Chair agrees, the protocol will be assigned to two IACUC members who will review it within about a week.

- **Administrative Review of Modifications:** Certain modifications can be approved outright by the IACUC Chair designee or the IACUC coordinator. These are: 1) Addition or deletion of research personnel, 2) Change or addition of funding source, 2) Room changes, as long as this space has already been approved for the studies proposed, 3) Termination of animal use, 4) Addition of \(\leq 10\%\) more animals of a species/strain already approved on the current ACORP, 5) Increase or decrease in concentration or dose of approved test substances, or adding analogous test substances (excluding chemical hazards, biohazards, and radioactive materials), 6) Referrals from the Chief Veterinary Medical Officer.

*The IACUC coordinator can provide forms and advise on submissions deadlines, IACUC meeting dates, etc.*

**Required forms for Animal Research include:**

1) ACORP (Animal Component of Research Protocol) forms.
2) Biosafety – SRS Forms.
3) Financial Conflict of Interest form(s)
4) New projects also need to include the grant or project narrative and the Request to Review form.

*The Animal Program Compliance Officer (APCO) can review the forms with you and assist with the lay language, power analysis, and literature search.*

**IACUC Decisions**

The IACUC may approve research, require modifications to the research to secure approval, or withhold approval (similar to being tabled).

**Approval:** Made when all criteria for approval are met.

**Modifications Required to Secure Approval:** (This is the most common outcome) Made when the IACUC requires specific modifications to the ACORP before approval can be granted. The IACUC will provide the PI with a memo detailing the required changes. The revised ACORP can then be approved by the IACUC members who did the initial review and does not need to go back to a convened IACUC meeting.

**Withhold Approval:** Made when the IACUC determines extensive changes to the ACORP are required. The IACUC will provide the PI with a memo detailing the required changes, and the revised ACORP will need to be reviewed at a convened IACUC meeting. In rare cases, the IACUC will withhold approval on the grounds that VA-GLA does not have suitable facilities, or the research is otherwise not appropriate. A PI may appeal this decision or s/he may redesign and resubmit the project as a new study.
Veterinary Medical Unit (VMU) Information

There are vivariums at both the West Los Angeles and Sepulveda campuses.

*Please consult with the Veterinary Medical Officer (VMO) about using these facilities, ordering animals, setting up breeding colonies, etc.*

**West Los Angeles campus**
Housing for mice, rats, hamsters, guinea pigs, gerbils, rabbits, cats, and dogs. The dogs are housed in indoor runs, plus there is an outdoor play area.

Specialty housing:
ABSL-2 housing for the following categories of studies:

- Pathogen studies, such as Leptospirosis or Cryptococcus.
- Tumor studies in immunodeficient animals.
- Animals treated with viral vectors to introduce genes, etc.
- There is also a room outside of the VMU for radioactively labeled mice.

Other facilities:

- Two operating rooms with isoflurane anesthesia equipment
- Post-op room with special heated cages
- A necropsy room
- A treatment room
- X-ray machine
- Two special procedure rooms with fume hoods
- Two ABSL-2 special procedure rooms with biosafety cabinets and isoflurane anesthesia equipment

**Sepulveda campus**

Housing for mice, rats, hamsters, guinea pigs, gerbils, rabbits, cats, and dogs.

Dogs are housed outdoors in very large enclosures, preferably in compatible groups. Each enclosure has a large, heavily insulated dog house with heating provided in cold weather and misting in hot weather.

Other facilities:

- Operating room with isoflurane anesthesia equipment.
- Procedure room with a sterile laminar flow cabinet.
- Treatment room.
Research Credentialing and Training Compliance

Credentialing refers to the systematic process of screening and evaluating qualifications and other credentials, including licensure, registration or certification, required education, relevant training and experience, and current competence and health status.

Employees need to be Research credentialed to be able to work on a Research project. The elements of the credentialing are:

**VA Appointment** (either VA paid or WOC): Any valid VA appointment and proof of status of appointment.

**Background Check:** Background check and fingerprinting are performed in the Human Resources Security office.

**Training:** Courses required for all research personnel are: 1. VA Privacy and Information Security and Rules of Behavior; 2. Government Ethics – The Essentials; and 3. Privacy and HIPPA.

*Please note: VHA Mandatory Training for Trainees course covers the three courses listed above. VA Mandatory Training for Transient Clinicians covers only Privacy and HIPPA and Government Ethics – The Essentials.*

Human Subjects (only if involved in human subject research)

Good Clinical Practices (only if involved in Cooperative Studies)

Laboratory Hazard and Research Safety/Biosafety (only if involved in lab based/animal research)

Working with the IACUC (for animal subject research) plus specific courses required by the Institutional Animal Care and Use Committee

**Five Exclusion Lists:** 1.) Office of Inspector General, Health and Human Services (HHS); 2.) Food and Drug Administration (FDA) list; 3.) Public Health Service Administration (PHS); 4.) System for Award Management (SAM); and 5.) Office of Research Oversight (ORO) Research Misconduct List.

**Scope of Practice (SOP):** Duties granted to the employee by the PI. SOP requires both the employee and PI signature. SOP is required one time unless duties have been changed and were not given on the original SOP. SOP is also required for the PI. In this case, the ACOS would be the PI and the PI would be the employee on the SOP.

**Education Verification:** Any and all educational degrees, regardless they are in the employee’s field of study, above high school.

**License Verification:** If a license is listed on your application or CV/Resume it must be verified regardless of the type of license even if it does not pertain to the duties that are assigned to the employee.

**CV/Resume:** Must be dated and **without** the date of birth and social security number

**VetPro:** If a dependent or independent licensed clinician.

**Occupational Health and Safety (OHS)** – Initial medical clearance is required for all that work in Research. It is required annually for those who work with animals and lab based research.
Volunteers, Students, Children

Volunteers for laboratory positions must be 18 years of age or older. **Anyone younger than 18 years of age is prohibited from working in research laboratories due to safety and liability issues.** Volunteers for other parts of GLA or in an administrative capacity may be less than 18 years of age. Paperwork to be recognized as a Volunteer at GLA is through the Voluntary Services Office located in bldg. 258, (310) 478-3711, ext 44284, 40906, or 40922. A Volunteer will be granted a VA identification badge and may receive a sticker to park a vehicle on VA grounds.

Students may be allowed to work in research laboratories if they meet the age requirements and are in an accredited University program that has a requirement to do laboratory research for coursework credit (e.g. Independent Study, Summer Research Program, etc.). Students in such programs are required to have a WOC appointment.
REQUESTING RESEARCH SPACE

The assignment and review of research space as well as the renovation of research space is under the purview of the Research Space and Renovations Subcommittee which is under the auspices of the Research & Development Committee. Research Service has been assigned space by the Medical Center to administer assignments and exercise overview of such space by Research Service. NOTE: VA space cannot be used by a VA Investigator or other third party for non-VA research unless there is appropriate legal authority to do so, and the parties enter into an appropriate real property agreement that complies with applicable law and VA policy, such as a Revocable License or lease.

Request for Research space can be made only by a Principal Investigator at GLA using the Space Request Form. This form is to be accurately completed in its entirety by the Principal Investigator requesting space and is to be forwarded to the ACOS for Research. The ACOS will review and forward the request to the Research Space and Renovations Subcommittee. The request will undergo several reviews including ones by the Research Biosafety Officer and the Animal Program Compliance Officer should the space be contemplated for use as a “wet” laboratory and/or animal research, to ensure the identified space is suitable for the needs of the Principal Investigator and in compliance with regulatory requirements. These reviews will take place prior to action by the full Committee.

Request for “dry” laboratory space (e.g. office space) generally used by Health Services Research will be reviewed by the Health Services Research representative to the Research Space and Renovations Subcommittee prior to full Committee review.

The CURE Digestive Diseases Center has been allocated research space by Research Service and CURE Principal Investigators must first request space through the CURE Director. Should CURE not be able to accommodate the Principal Investigator, the space request can then be forwarded to the ACOS for consideration by the Committee.

Surgical Principal Investigators must initially request space from the Chief, Surgery and Perioperative Care as Surgery has been allocated research space by the Medical Center. Should Surgical Service not be able to accommodate the request, the Principal Investigator can then request space through the Committee.

Overall, office space for researchers is at a premium and thus Principal Investigators with an office in the Medical Center will not be allotted an additional research office.
Research space is reviewed by the Research Space and Renovations Subcommittee on a periodic basis. In general, active research funding and/or active pursuit of research funding, research productivity, contribution to research via collaborations, mentoring of junior investigators and trainees, among others, are all taken into consideration when space is reviewed. Space may need to be reassigned based on needs of new and/or expanding research programs from those programs that have not shown activity or productivity.

Should the Principal Investigator identify space that is not under the purview of Research Service, and thus deemed to be Medical Center space, a request must first be made to the Research Service Space and Renovations Subcommittee to endorse the application, and the Principal Investigator must then apply to the Medical Center Space Committee through his/her Service Chief. Generally, Facilities Management will perform the initial review of the request.

Potential renovations to Research space must also be approved the Research Space and Renovations Subcommittee even if the Principal Investigator has the funding to accomplish the renovations and is not asking VA funding to fund the renovations.

**Space Disbursement**

Investigators or groups of Investigators who wish to appeal a decision regarding research space may submit a written request to the Chair, R&D, within ten working days after notification of the decision. Appeals may be denied by the R&D Committee or the R&D Committee may refer the matter back to the Research Space Subcommittee for reconsideration. Investigators who wish to meet personally with the Committee should include that request in the written appeal.

Space may be **assigned** to an established independent Investigator (e.g. Principal Investigator on Merit Review or RO1), or space may be **loaned** to junior Investigators (transition from Career Development to independent status, private foundation or other exploratory type grant meant to secure preliminary data) or to independent Investigators who meet the criteria:

1.) Research programs funded by VA merit review, or similar VA funding.

2.) 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.

3.) Non-peer reviewed research supported by extramural funding with high priority or relevance to the care of Veterans.

4.) Common resource research activities (e.g. use of equipment, research techniques, or focused interests).

5.) Productivity: This will be judged by publication of substantive papers in critically-reviewed journals.

6.) Clinical relevance of the Investigator: This factor will be based on an Investigator’s primary clinical responsibilities (e.g. recruitment/retention of rare or selected critical specialties).
Space authorized for conducting a research program will be committed to the Investigator for the length of the funding of the specific program. Career Development Awardees (whatever the source of funding) will be housed in space of their mentor(s). Career Development Awardees transitioning from trainee status to independent status will be loaned space until it is deemed by the Research Space Subcommittee with approval by the R & D Committee that independent funding for a research program has been established.

Every effort shall be made to not disrupt ongoing research programs and laboratory space will not be reallocated unless dictated by necessity. However, when an Investigator’s support is terminated and it is determined that the Investigator is not competitive in acquiring future support within a reasonable time the space previously used by that Investigator may be reallocated to another Investigator based on established guidelines. Thus, space allocated to an Investigator or Investigator group program will revert to Research Service should the Investigator or Investigator group no longer utilize the space effectively for research. Space will not be “bequeathed” by one Investigator to another.

Office space for Clinician-Investigators will be allowed in research space only as long as the office space in research is the primary and only office space held by the Clinician-Investigator. Clinician-Investigators with offices in patient care areas may be allocated office space in research space if defined office space is available or if the Investigator wishes to convert laboratory space into an office area. The conversion of laboratory space to office space must first be approved by the Research Space Subcommittee and the R&D Committee and the conversion of laboratory space to office space, if approved, must be funded by the Investigator.

**Annual Review of Space:**

Review of research space will be conducted on an annual basis. Useable research space will be reallocated and prioritized as outlined above. In addition, the following considerations will be taken into account (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.) Impact on collaborations, core facilities, equipment, etc.
4.) Personnel versus equipment requirements of the project.
5.) RDIS II Report of most recent reported research expenditures.
6.) History of grant/contract funding and proposal submission.
7.) Publication history.
8.) History of having non-VA grants/contracts administered through the VA non-profit corporations will be given preference for VA research space.
NON-PROFIT RESEARCH AND EDUCATIONAL CORPORATIONS AT GLA

While the VA supports its own research program with allocated funding, investigators within the system are allowed and encouraged to seek support for their research endeavors from other agencies, such as the National Institutes of Health (NIH) and the Department of Defense (DOD). In addition, the medical device and pharmaceutical industries frequently seek settings in which to conduct research on products being developed and VA Medical Centers are often appropriate venues for this work. Whether from public or private sources, these funds for specific projects are maintained separately from the funds to operate the medical facility. These monies previously were administered as “post funds” until VHA provided an option to VA Medical Centers that engage in research activity for the establishment of Non-profit Research and Educational Corporations.

In 1988, Congress passed legislation that allowed VA medical centers to establish nonprofit research corporations (NPCs), forming a unique partnership that dramatically broadened VA’s ability to accept private and non-VA public funds to support VA’s research program. Details of the public law can be found at the National Association of VA Nonprofit's website: http://www.navref.org/

Investigators who have the appropriate permissions from GLA R&D can have BBRI or SRC administrate non-VA funded research and/or administer a ‘Various Donors’ fund for unrestricted donations for research. The non-profit will assist the investigator in the process of negotiating a workable budget, which would include all cost reimbursements to the GLA for services they provide to the protocol. The non-profit will also generate the required contract or Cooperative Research and Development Agreement (CRADA) with the Sponsor for the work being considered. Contracts will not be signed by the non-profit until the PI provides a copy of the GLA R&D approval letter for the protocol. In addition, the non-profit will continue to maintain its administrative responsibilities to the project as long as the GLA R&D approval remains active.
Sepulveda Research Corporation and Brentwood Biomedical Research Institute

The missions of Sepulveda Research Corporation (SRC) and Brentwood Research Institute (BBRI) is to improve and advance the health and well-being of Veterans by supporting research and education conducted at the Veterans Affairs Greater Los Angeles Healthcare System. Established in 1989, as a 501 (c)(3) California corporation, created pursuant to title 38 §§ 7361 through 7366, United States Code (U.S.C.).

Our primary goal is to establish and maintain a productive and quality working relationship with our investigators. SRC and BBRI is dedicated in supporting and promoting biomedical research and related educational activities at the VA Greater Los Angeles Healthcare System (GLA). The non-profits provide a flexible funding mechanism for research activities including the receipt and administration of research funds other than Veterans Administration appropriations.

GLA System is the largest healthcare system within the Department of Veterans Affairs. It is one component of the VA Desert Pacific Healthcare Network (VISN22) offering services to Veterans residing in Southern California and Southern Nevada. GLA consists of three ambulatory care centers, a tertiary care facility and 10 community based outpatient clinics. GLA serves Veterans residing throughout five counties: Los Angeles, Ventura, Kern, Santa Barbara, and San Luis Obispo. There are 1.4 million Veterans in the GLA service area. GLA is affiliated with both the David Geffen School of Medicine at UCLA and Keck School of Medicine of the University of Southern California, as well as more than 45 colleges, universities and vocational schools in 17 different medical, nursing, paramedical and administrative programs.

GLA directs the Department of Veterans Affairs’ largest educational enterprise. We serve as a major training site for medical residencies sponsored by the David Geffen School of Medicine at UCLA and USC School of Medicine, as well as more than 45 colleges, universities and vocational schools in 17 different medical, nursing, paramedical and administrative programs.

Over 500 University residents, interns, and students are trained at GLA each year. The institution sponsors 16 medical residencies and numerous associated health residencies and internships in dentistry, podiatry, optometry, pharmacy, clinical psychology, social work and dietetics.
VA TECHNOLOGY TRANSFER PROGRAM

Overview

The mission of the VA Technology Transfer Program (TTP) is to serve the American public by translating the results of worthy discoveries made by employees of VA into practice. This requires a program that educates inventors concerning their rights and obligations, rigorously evaluates all inventions, obtains patents, and assists in the commercialization of new products. It also requires consistent policies that govern the necessary relationships between investigator (i.e., inventor), academic partners, local VA medical centers, industry, and the Department of Commerce. It requires close collaboration between ORD and the VA Office of General Counsel (OGC).

The TTP public mission requires aggressive dissemination of educational information to investigators and of products to the market. It is also necessary that VA assert an ownership interest whenever appropriate, so that discovery can be built upon. This ensures access to technologies by Veterans.
MATERIAL TRANSFER AGREEMENTS

Investigators may need reagents (antibodies, biochemicals, etc.) or special genetically engineered animals, or other research materials that may not be commercially available. Pharmaceutical, biotechnology companies, Academic Institutions, or other private foundations may have such research materials and may be willing to share them with the Investigator. In most cases a Material Transfer Agreement is executed between the Investigator, the supplying entity, and GLA. The ACOS, Research & Development or Deputy ACOS Research & Development are authorized to execute such a Material Transfer Agreement on behalf of GLA. Conversely, reagents or other research materials developed by a VA Investigator and requested by a non-VA scientists are also subject to MTAs.

Templates for MTAs are available at the VA ORD Technology Transfer website at vaww.research.va.gov under “Program” then “Model Agreements.”

Invention Disclosures: Patentable ideas, discoveries, etc. are encouraged to be submitted to the Tech Transfer Office. A report of Invention and Certification Forms (one Certificate per VA investigator) should be completed and forwarded to the ACOS, Research. Dual appointees (e.g. VA and University affiliate) must also submit to the academic affiliate since the VA has a formal Cooperative Technology Administration Agreement (CTAA) with both University of California and University of Southern California.

Remember that the rights to any discoveries or inventions made with VA resources (Investigator time, space, etc) may be claimed by the Federal government under Executive Order 10096.
EQUIPMENT INVENTORY LIST (EIL) AND EQUIPMENT TURN-IN AND TRANSFER

Each Investigator purchasing equipment from VA appropriated funds must have an Equipment Inventory List (EIL) established. The EIL had previously been called the CMR. The Investigator can request to establish and EIL through Acquisition and Materiel Management (A&MM) memo to Assistant Chief, PPM Section. Assistant Chief, PPM Section can be reached in bldg 218, room 113 at (310) 478-3711, ext 42758 or by FAX at (310) 268-4666. Upon approval by Assistant Chief, PPM Section, an EIL number will be assigned in Inventory Management. Inventory Management can be reached at bldg 218, room 113 at (310) 478-3711, ext 42749.

On an annual basis, each Investigator with an EIL will be asked to confirm that equipment on the EIL is accounted for. This has been simplified by bar coding identification numbers on each item purchased through VA appropriated funds. If VA-purchased items do not have a bar code, please contact Tadzio Kowlczyk, ext 42749 in A&MM.

Turn-in of outdated or equipment that is beyond repair is done on a VA Form 90-2237, Request, Turn-in and Receipt for Property or Services (or “2237”). This form can be obtained from the VA Intranet or from the Research Biosafety Officer (310) 478-3711, ext 41303. The Research Biosafety Officer will arrange for pick-up and disposal of equipment slated for turn-in.

Equipment on an active VA Investigator’s EIL can be transferred to another VA Investigator. Again, the VA Form 2237 can be used to document the transfer. However, equipment on the EIL of a VA Investigator who will be leaving the Medical Center will revert back to Research Service. Such equipment can be made available for new Investigators moving to the VA, for any VA Core Facilities, or to other Investigators having need for such equipment.

In rare circumstances, equipment may be needed to be taken off the VA station. In these cases, a request for removal of equipment from the VA and justification for such removal must be made to the ACOS, Research & Development in writing. If approved, the Investigator will then complete a property pass obtained from Acquisition and Materials Management.

Equipment purchased with funds from the Universities or purchased through the VA non-profits (Brentwood Biomedical Research Institute or Sepulveda Research Corporation) is the property the respective organizations. Any turn-ins or transfers must be handled by these organizations.
Veterans Equitable Resource Allocation (VERA)

The Research Support is funded as a separate component of the VERA model because research missions vary from Network to Network. In addition, research support is the only component of the VERA model that is computed at the facility level. The VERA methodology for allocating research support dollars is based upon the following two factors that are determined each year: 1) the research support budget and 2) the volume of research grant dollars that are discounted in accordance with the weighted value of the funding source.

Research Support Budget: In recent years, the VERA research support budget has equated to approximately one half the value of the VA administered research grants for the given year. However, it is important to note that the research support budget is determined each fiscal year as part of the budget process, and may be subject to change.

Research Support from the Medical Care budget includes:

- Personal services costs for individuals on the Medical Care rolls who spend part of their time working on research projects;
- Facilities costs (Engineering, Environmental Management, utilities, etc.)
- Administrative costs (Fiscal, Human Resources, Acquisition and Material Management, etc.)

Process for Distributing Research Support Funds:

Research offices enter and transmit research project data to the Office of Research & Development (ORD) via the ePROMISe system. The ORD Central Office produces a report that weights (discounts) the research expenditure based on the grant’s funding source as indicated in the chart below. This report identifies the fiscal year Discounted Grant dollars for all VA facilities and is used to allocate the research support dollars. ow VERA is calculated

1. VAMCs submit their expenditures in the various categories
2. Weighted sum is calculated for each VAMC
3. Weighted total from all VAMCs is summed
4. The total requested is divided by the total available to get the “national price”
   e.g. if national total = $1,000M
   and the available VERA allocation is $580M
   the national price is $580 / $1,000 = 58%
5. Each VAMC’s weighted total is multiplied by the national price to get final allocation for that site
6. Funds are sent to VISN who distributes to VAMCs

VERA dollars come two years later

1. VAMCs report totals at the end of FY16
2. VERA calculated over FY17
3. Funds distributed in FY18
## Research VERA Chart

<table>
<thead>
<tr>
<th>Weight</th>
<th>Who administers</th>
<th>Type of funds</th>
<th>Fund Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>VA or VA-NPC</td>
<td>• VA Research funds</td>
<td>• VACO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• QUERI</td>
<td>• NIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reimbursed by other Federal agency</td>
<td>• Other Federal Agency (e.g. DOD, CDC, NSF, FDA, NASA...)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• VA General Post Funds</td>
<td>• Academic Institution, Donor or State/Local Government</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Funds awarded to NPC</td>
<td>• Private Proprietary Company (Industry)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Voluntary Agency or Foundation (e.g. AHA, PVA..)</td>
</tr>
<tr>
<td>75%</td>
<td>Not VA; Administered by academic affiliate or other</td>
<td>• Peer reviewed</td>
<td>• NIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Other Federal Agency (e.g. DOD, CDC, NSF, FDA, NASA...)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Voluntary Agency or Foundation (e.g. Am. Heart, Am Lung, PVA..)</td>
</tr>
<tr>
<td>25%</td>
<td>Not VA; Administered by academic affiliate or other</td>
<td>• NOT Peer reviewed</td>
<td>• Academic Institution, Donor or State/Local Government</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Private Proprietary Company (Industry)</td>
</tr>
</tbody>
</table>
REPORTING GUIDELINES FOR
RESEARCH & DEVELOPMENT INFORMATION SYSTEM (RDIS),
INVESTIGATOR EXPENDITURE REPORT (Page 20*)

1. The accurate reporting of Investigator Expenditures for each FY is crucial to Research Service and to the Medical Center since a portion of the Veterans Equitable Resource Allocation (VERA) coming back to the Medical Center is derived from the Investigator Expenditure Report. Underreporting resulted in a proposed two million dollar cut to the VA GLA Healthcare System budget for FY 2017 and a four million dollar cut to the VA GLA Healthcare System budget for FY 2016.

2. There has been confusion over the years with regards to which Investigators should report, and if grants and contracts are at multiple administering agencies (i.e. VA, Universities, VA-nonprofits, RAND, etc.), what portions should be reported. In this regard, there has been either under-reporting or over-reporting of Investigator Expenditures.

3. The following are guidelines relative to the reporting process and data that should be included:

   1. The Investigator Expenditure Reporting document is found in the Research and Development Information System (RDIS) Page 20. This form will go out to all Investigators in our Research database here at the VA.

   2. VA expenditures and expenditures through the VA non-profits (both BBRI and the SRC) will be obtained and entered by the Research Administration staff.

   3. University expenditures will need to be reported by:

      a. VA-employed Investigators with 5/8 FTEE or greater or who are otherwise eligible for VA funding even if less than 5/8 FTEE who are Principal Investigators or Co-Principal Investigators.

      b. VA-employed Investigators with less than 5/8 FTEE who have not been granted eligibility for VA funding but are Principal Investigators or Co-Principal Investigators on non-VA-administered grants (e.g. VA non-profits, Universities, RAND, etc.), where the work is done in total or in part at the VA.

      c. WOCs with base of operations (laboratory, main office) here at the VA who are Principal Investigators or Co-Principal Investigators.

      d. WOCs who are Principal Investigators or Co-Principal Investigators and who have a base of operations elsewhere but who perform studies or do any other research work on VA premises or recruit VA subjects.

4. VA-employed Principal and Co-Principal Investigators with 5/8 FTEE or greater or otherwise eligible for VA funding will report all of their University and/or other agency administered expenditures for research from grants, contracts, various donors accounts, etc. for the institutions Fiscal Year.

   *Copy of Page 20 is located in Appendix C
5. VA-employed Principal and Co-Principal Investigators with less than 5/8 FTEE should report University and/or other administered expenditures for all projects executed at the VA. If only part of the work is done at the VA, expenditures should be reported for that portion done at the VA. Reporting should be for the VA fiscal year which runs from October 1 through September 30.

6. WOC Principal and Co-Principal Investigators with their base of operations at the VA will report all of their University and/or other agency administered expenditures for research from grants, contracts, various donors’ accounts, etc. Reporting should be for the VA fiscal year which runs from October 1 through September 30.

7. WOC Principal and Co-Principal Investigators who have a base of operations elsewhere (not on the VA grounds) but who perform studies at the VA or using VA patients will report that proportion of expenditures from University and/or other agency-administered research grants, contracts, various donors accounts, etc. that were in support of the research done at the VA or on VA patients for the VA fiscal year which runs from October 1 through September 30.

8. Investigators who are WOC Co-Investigators but where the PI or Co-PI of the grant is VA-employed (irregardless of FTEE eighths) and where expenditures are incurred for grants, contracts, etc. where part of the work is done at the VA should report only expenditures for work done at the VA. In all cases, the WOC Co-Investigator must ensure that the VA-employed PI and/or Co-PI have not reported an identical expenditure.

9. Investigators who are VA-employed Co-Investigators (regardless of FTEE eighths) and where the PI and/or Co-PI are WOC and where expenditures are incurred for grants, contracts, etc. where a part of the work is done at the VA, should report only expenditures for work done at the VA. In all cases, the Co-Investigator must ensure that the WOC PI and/or Co-PI have not reported an identical expenditure.

10. Expenditure reports are due in the Research Office by COB of the first working day of each new fiscal year.

11. All Investigators who have VA-approved research projects are required to submit a copy of all new notices of research grant awards delineating the start and end dates of the award and the award amounts for each year of the award (even if administered by the Universities or other administering agencies to their VA Department Chair and to the VA R&D office.

Total GLA Research Expenditures for last 5 years

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>$38,679,642</td>
</tr>
<tr>
<td>2016</td>
<td>$36,696,754</td>
</tr>
<tr>
<td>2015</td>
<td>$40,565,700</td>
</tr>
<tr>
<td>2014</td>
<td>$40,794,874</td>
</tr>
<tr>
<td>2013</td>
<td>$39,905,982</td>
</tr>
</tbody>
</table>
Research Service Budget

Ordering Supplies and Equipment

Investigators at GLA may have research funds administered by the following sources:

1) VA (either appropriated funds or General Post funds);
2) University (either Cedars-Sinai, UCLA, or USC);
3) VA non-profit research corporations (Brentwood Biomedical Research Institute (BBRI) and Sepulveda Research Corporation (SRC).

No other administrative sources for research funding is allowed for
a) full- or part-time VA employees;
b) where any part of the research work is being done on VA grounds.
c) Ordering through the Universities and the VA non-profit research corporations are handled by these respective acquisition offices (Investigators should check with their University Departments for the locations and contact personnel. BBRI is located in bldg. 114, room 217; SRC is located in bldg. 200, 3rd floor, room 3232).

Ordering through the VA is done in bldg 114, room 300. PIs located at WLA should contact Edward “Mike” Montgomery. PIs located at Sepulveda should contact Janice Thompson. Each PI who has VA research funding or an account in the VA Research General Post Fund has pre-printed ordering forms that specifies the account number and cost centers from which supplies and equipment can be purchased. These forms are available through the above contacts.

The form for ordering isotopes has a signature line for the Radiation Safety Officer to approve acquisition of radioisotopes to be used in research. This approval must be obtained prior to submission of the isotope order. Usually these orders are Urgent in nature, and next day delivery is required.

The order form for ordering animals needs to be accompanied by VMU approval. Animals are delivered to the VMU on Tuesdays only.

The order form is self-explanatory and should be filled in completely. Although Mike or Janice usually get GSA pricing on most items requested when an order is placed with the vendor, Investigators or their staff person(s) filling out the order request may want to call the vendor in advance to see if the vendor offers GSA pricing.

Please specify when the order should be received. Orders are placed within a timely manner upon receipt of the order requisition in bldg 114, room 300.
Please specify the location to where the order should be delivered. With isotope orders, all isotopes are to be delivered to: General Warehouse, bldg 297 with the ATTENTION line of “Research / PI’s name”. Once radioisotopes arrive, they are initially delivered to the RSO to be sure that they are logged in to the Medical Center permit inventory as well as the individual PI’s internal permit inventory. The RSO office will then call the PI’s laboratory for pick-up of the received radioisotope.

Equipment requests larger than $3,500 are placed on a 2237 form. All Service request larger than $2,500 will also need to be processed on a 2237 form. Depending on what you are ordering whether it is a supply or service will depend on what you need in the purchasing package. The forms for the package can be obtained from the Budget Office. Any help or assistance understanding the forms are provided on an as needed basis from Jennifer. Once the budget office checks for adequacy of funds in the PI’s account, the request package is checked for accuracy and ensures that all the appropriate paperwork is filled out the order is routed to the corresponding contracting office either:

1) Network Business Center in Long Beach
   or
2) The Research Contracting Office (RCO) in Pittsburgh, PA for further processing.

Further justifications for a “sole source vendor” should be made explicitly clear as to the reason for “sole source” necessity. Otherwise, if an identical piece of equipment or service can be found from other vendors, a bidding process may ensue to try to get the item at lowest cost.

It is mandated by a Supreme Court ruling that preference is given to Veteran owned business. If the preferred vendor is not Veteran owned the purchase will take longer to be completed. Generally for equipment and supplies our contracting officers can find Veteran owned business who provide the items and competitive rates.

Ordered equipment is automatically recorded to the PI’s Equipment Inventory List (EIL), formerly known as a CMR. Equipment ordered is first delivered to bldg 297 (General Warehouse) for appropriate bar coding for inventory.

Service contracts, contracts for consultants or other work are requested through a 1358 form. These forms can also be obtained in bldg 114, room 300. These requests must also be processed through the Network Business Center and may take as short as one day or up to several weeks.

The procurement process does not begin until these forms are turned into the Budget Office. Contracting requests can take up to 30-60 days or more from request to completion, please be patient.

Once the contract request package is turned into Research Budget, all communication with the lab to the vendor needs to stop. Please direct all your questions and concerns with the Budget Office.

Received items are usually accompanied by a packing slip or sometimes an invoice. It is the PI’s responsibility that the packing slip and/or invoice is delivered back to bldg 114, room 300 in the “Packing Slip/Invoice” receipt box. Reconciliation of charges is done with the packing slip and/or invoice. Items not received can be tracked using the assigned vendor tracking number and/or the assigned VA purchase order number.
investigator budgets and employee benefits

a few issues commonly arise, that cause problems with the budget.

salaries: VA grants should be written with 30% overhead for salaries. This is an estimate for all costs including FICA (social security), FERS (retirement), Medicare, thrift saving, health & life insurance, and annual & sick leave. Since at the time of the grant submission, it may not be known who will take the position, this overhead accounts for the highest possible costs to be incurred by the investigator. Most of the changes in cost are related to health insurance benefits (e.g. single individual vs. family policy).

annual leave: Annual leave is “cashed out” when an employee terminates. This occurs at the termination grade and step and is incurred by the investigator employing the employee at time of termination regardless of length of service for that investigator. The best policy is to ensure that employees take leave within the year incurred and do not carry over high levels of annual time. The other possibility is to account for this at the end the grant period and terminate the employee a month early so that the “cash out” will cover that month’s salary. These costs can be quite large depending on the employee’s grade/step and length of employment.

sick leave: Sick leave is not “cashed out” upon termination but can be restored for a terminated employee if the employee returns within 2 years to VA service.

leave without pay: This type of leave should not be used for long time absences. It is the responsibility of the ACOS/R&D (not the investigator) to approve leave without pay for up to 30 days if the investigator or employee is a Research Service employee (T&L Cost Center from Research). There are tremendous budgetary effects of using this type of leave as well. The employee accrues annual & sick leave as normally for quite some time before HR figures out that this is incorrect. The employee then has annual & sick leave deducted from their account. If the employee terminates before HR deducts the over amount of the annual leave, the employee will be responsible for returning money paid for that leave.

A summary of the benefits provided by each type of employment are listed below. Refer to the GUIDE TO PERSONNEL POLICIES for full explanation of hiring and benefits policies associated with each type of employment.

<table>
<thead>
<tr>
<th>Employment type</th>
<th>Annual leave/sick leave</th>
<th>Health/life insurance</th>
<th>Length of appointment</th>
<th>Grade of appointment</th>
<th>Competitive appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special needs</td>
<td>X</td>
<td>X</td>
<td>60 days</td>
<td>any</td>
<td>any</td>
</tr>
<tr>
<td>Exempted</td>
<td>X</td>
<td>X</td>
<td>&lt;1 year</td>
<td>any</td>
<td>X</td>
</tr>
<tr>
<td>Term</td>
<td>X</td>
<td>X</td>
<td>1-4 years</td>
<td>any</td>
<td>X</td>
</tr>
<tr>
<td>Schedule B</td>
<td>X</td>
<td>X</td>
<td>&gt; 4 years</td>
<td>≥ GS11</td>
<td></td>
</tr>
<tr>
<td>Schedule A</td>
<td>X</td>
<td>X</td>
<td>while student</td>
<td>≤ GS7</td>
<td></td>
</tr>
<tr>
<td>Temporary</td>
<td>X</td>
<td>X</td>
<td>&lt;1 year</td>
<td>≤ GS12</td>
<td>X</td>
</tr>
<tr>
<td>IPA</td>
<td>X</td>
<td>X</td>
<td>4 years</td>
<td>any</td>
<td></td>
</tr>
</tbody>
</table>

holiday benefit day

If a holiday is on Monday thru Saturday (day off) the previous day will be in lieu of holiday. If a holiday is on Sunday (day off) the next work day will be the in lieu of holiday

<table>
<thead>
<tr>
<th>Holiday Falls on...</th>
<th>Sunday Day Off</th>
<th>Monday Day Off</th>
<th>Tuesday Day Off</th>
<th>Wednesday Day Off</th>
<th>Thursday Day Off</th>
<th>Friday Day Off</th>
<th>Saturday Day Off</th>
</tr>
</thead>
<tbody>
<tr>
<td>holiday moves to...</td>
<td>Next Work day</td>
<td>Previous Work day</td>
<td>Previous Work Day</td>
<td>Previous Work Day</td>
<td>Previous Work Day</td>
<td>Previous Work Day</td>
<td>Previous Work Day</td>
</tr>
</tbody>
</table>
Animal Purchasing Procedures

NOTICE: Do not place an animal order without the express approval of the Veterinary Medical Unit (VMU) and the Research and Development Office.

Animal Ordering

"Animal ordering" includes the introduction of any live vertebrate animal from any source to be housed and/or used in research by persons at the GLA. Sources of animals include commercial vendors, other colleges and universities, pet stores, wild caught, donations, and investigator reared animals. Uses include research, testing, demonstration, teaching, and holding.

Principal Investigators (PI) are responsible for following these procedures whenever animals are ordered. The PI should inform assistants and associates of these procedures.

The Veterinary Medical Unit - Orders can only be approved by the Chief Veterinary Officer (VMO), Assistant VMO, or a VMU Supervisor. Technicians cannot approve animal orders.

The Veterinary Medical Unit supervisory personnel will review Animal Order and Request for Animal Care forms, approve orders as appropriate, and prepare for animal arrivals in a timely manner. Problems with pending orders will be communicated to the PI or his representative.

Procedures to be followed by investigators before ordering animals:

2. Sufficient funds must be available to cover normal and special VMU charges.
3. VMU approval for Each Animal Delivery - The VMU must approve each animal order.
   1. Your animal order will be approved if space, caging, and other required equipment are available.
   2. Ordered from an approved vendor and be virus antibody free

Submit an Animal Order and Request for Animal Care form (attachment 2) for each delivery at least two (2) weeks in advance to VMU. More time (3 to 4 weeks) may be required when:

(1) investigator orders for the first time,

(2) there is a very large animal order, or (3) unusual species or housing conditions require special preparation.

The form, Animal Order and Request for Animal Care, should be FAXED or dropped off at the following locations:

<table>
<thead>
<tr>
<th>Campus</th>
<th>Supervisor’s Phone</th>
<th>FAX</th>
<th>Bldg. And Room No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepulveda</td>
<td>818-895-7870</td>
<td>818-891-7711</td>
<td>47, Supervisor’s office</td>
</tr>
<tr>
<td>WLA</td>
<td>310-268-4650</td>
<td>310-2684851</td>
<td>117, room. 10</td>
</tr>
</tbody>
</table>
VMU personnel check these locations daily. Forms will be returned the next day. If you have questions regarding animal orders call the VMU supervisor in your area or call the CVMO at 310-268-3515.

**IT WILL COST YOU MORE IF YOU DO NOT PROVIDE VMU WITH THE PROPER NOTIFICATION!**

*Animal Order and Request for Animal Care* forms that are not received at least 6 working days in advance will be subject to a **$20 service fee** to cover the increased costs of an emergency order. Your regular animal care account will be charged along with your per diem.

Obtain additional approval from Research & Development

Orders are generally placed through the Research and Development Office (R & D) or the non-profit foundation. Do not place animal orders directly without the express written approval of R & D.

Animals must be ordered from an approved vendor and be virus-antibody-free unless other arrangements have been made with the VMU.
SUBMISSION OF MANUSCRIPTS AND ABSTRACTS

1. All manuscripts submitted for publication, both peer-reviewed and non-peer-reviewed, including book chapters, and reviews must be submitted for review by the Research & Development Committee. Additionally, all abstracts submitted for presentation to local, national, or international scientific meetings must be submitted for review by the Research & Development Committee.

2. All manuscripts and abstracts submitted for review should have the authors identified by their appropriate VA affiliation. In the case of VA Career Development Awardees, the VA should appear as the primary affiliation. Additionally, VA FTEE 5/8 or greater the VA must be listed as the primary affiliation. Manuscripts where the work was done at the VA should acknowledge the VA. Work done with the support of a VA Merit Review, VA Cooperative Study, or other VA funding should acknowledge the VA funding source. Failure to acknowledge VA support or employment may result in the discontinuation of current VA R&D funding and/or ineligibility to receive future R&D funding for up to 5 years.

3. Manuscripts or abstracts for review should be submitted to the Secretary, Research Service, bldg 114, room 330 or electronically to the ACOS, Research. Such items for publication will be placed on the agenda for the next Research & Development Committee review if submitted at least one week prior to the next Research & Development Committee meeting (last Wednesday of every month).

4. All publications are required to be entered into the VA Central Office SharePoint PubTracker upon notification that the manuscript or abstract has been accepted for publication or presentation.

Publication Tracker: [http://vaww.pubtracker.research.va.gov/PubTracker/default.cfm](http://vaww.pubtracker.research.va.gov/PubTracker/default.cfm)

Procedures for Research Staff Contact with Professional Journals:

a. The Public Affairs Office will not manage researchers' interaction with Professional Journals. However, researchers are responsible for keeping the Public Affairs Office updated on any issue related to materials accepted for publication for the purpose of publicizing the accomplishments of our research staff.

b. A Public Affairs Officer will coordinate all public statements, news releases and Media interviews with a VA Central Office research representative.

c. In the event that a professional journal requests the embargo of press releases until the publication date, Public Affairs will observe such requests to preserve the VA's relationship with the journal but will develop a plan, as appropriate, for publicizing the accomplishments of the researcher(s).

Public Access

VA investigators must make available to the public all peer-reviewed publications reporting the results of ORD-funded research, without restriction, in accordance with VHA Handbook 1200.19. To meet this requirement, investigators are responsible for depositing manuscripts in PubMed Central, operated by the National Institutes of Health's National Library of Medicine (NLM), upon the manuscripts' acceptance for publication. Articles with a publication acceptance date of February 1, 2015, or later are to be included. Deposited manuscripts are made available to the public in PubMed Central no later than 12 months after their publication in a journal. For specific procedures for depositing manuscripts, please visit the following NIH page: [http://www.ncbi.nlm.nih.gov/pmc/](http://www.ncbi.nlm.nih.gov/pmc/)

Please note that depositing manuscripts in PubMed Central does not satisfy the requirement, per VHA Handbook 1200.19, to notify VHA Research Communications of any upcoming publications or presentations, upon their acceptance, through the PubTracker system. To learn more about this requirement go to [http://www.research.va.gov/resources/policies/pub_notice.cfm](http://www.research.va.gov/resources/policies/pub_notice.cfm).
1. News media and other individuals outside VA may not understand the contributions and roles of VA in intellectual advances, or VA’s collaborative relationships with universities and other affiliated institutions. Accordingly, scientists and physicians with VA salaries and/or funding support or receiving VA support with respect to research and/or office space, or other VA resources used in accomplishing the research, when presenting their work or discussing it with the news media, **make a serious and good-faith effort to obtain appropriate recognition for VA**. A serious and good-faith effort requires:

   (1) Securing a verbal agreement that VA will be cited in news reports **before** participating in a media interview, or

   (2) Prior to interviews, providing news media with a document on VA letterhead that:

      (a) contains the investigator’s name, VA title, and VA medical center
      (b) explains that the investigator’s research funding from VA depends upon proper citation of his/her VA employment in all publicity about his/her research activities, and
      (c) expresses a preference that the investigator’s VA title be used when media time or space limitations permit the use of only one professional title.

2. Investigators who are called upon by the media to give an interview about their work should have the interview first cleared with the Public and Consumer Affairs Office. This can be done by having the news media contact Public Affairs at (310) 268-3790 or by FAX at (310) 268-4868 or by e-mail on Exchange. Alternatively, the investigator should contact the Public and Consumer Affairs Office if the news media has not done so first. The investigator should also let the Research Office know of the potential media coverage. The Research Office will notify VA R&D Communications. Information regarding interview by the media should be entered into PubTracker by the Investigator.

3. Any manuscript that is to be published in a high impact journal of wide scientific and/or clinical interest (e.g. Nature, Science, New England Journal of Medicine, British Medical Journal, JAMA, etc.) should notify the Research Office when research results are accepted for publication. The Investigator should include an abstract of the study, a brief (1-3 sentence) statement of the study’s central finding(s) and potential impact, the name of the journal and the anticipated publication date. The Research Office will then notify VAHQ R&D Communications and the local Public Affairs Office. In parallel, the Investigator should enter the manuscript into PubTracker.
COMPUTER SUPPORT

Departmental services include:

1. Maintenance of communication with investigators through email alerting them to important information.
2. Maintenance of the Research Service web site, which includes revising various forms/manuals/information.
3. Maintenance of Research Service directory, which will include PIs and brief description of their research programs submitted by the PIs.
4. Troubleshooting for research databases (e.g. ePROMISe, RPMS, RPTS, budget)
5. Development of a paperless system for filing forms.

Services for investigators include:

1. Organization of computer connections through Information Technology (IT) including request for New Technology (NT) and Outlook accounts, codes necessary to access VISTA, CPRS. Research
2. Provides assistance with the VA Talent Management System (TMS), including entry into system, reactivating users, passwords and troubleshooting. Provides assistance with CITI, including password reset and troubleshooting. TMS Research coordinator is Dr. Sharon Saivar, Sharon.Saivar@va.gov
3. Provides assistance with computer questions, not answered by the Help Desk.

Computer systems available:

1. VISTA – This system is used for employees to request leave, review their employee record, and is connected to clinical system (CPRS). The access and verify codes for VISTA are the same as the CPRS codes. VISTA is used by the ADPAC coordinator to assign Research menus, access keys, title corrections, reset verify codes, add accounts, and CPRS.
2. VA Intranet and Research Web page – these systems are available at most computers within the facility and require a NT account to access. They are for information only and any forms or templates should be saved using the “save-as” or “save target as” function into personal hard drives prior to utilizing them.

Public Key Infrastructure (PKI): PKI is a set of hardware, software, people, policies, and procedures needed to create, manage, store, distribute, and revoke digital certificates. If you already have VA PIV (Personal Identification Verification) card your PKI certificates are already incorporated in your PIV card and available for use.

Virtual Private Network (VPN): Remote Access is allowed and controlled through the National One VA VPN. The National One VA VPN controls all remote accesses through a managed access control point. All requests for One VA VPN accounts must be approved by the immediate supervisor, the IT Chief/CIO and the ISO. The National One VA VPN uses a “time-out” function that requires re-authentication after 30 minutes inactivity.

Personal E-mail - In April 2015 the VA CIO, published a memorandum forbidding the use of personal e-mail to conduct government business. Fact Sheet was Created by the VHA records Management Council in January 2018 the VA OGC, published another memorandum again limiting the use of personal e-mail accounts to emergencies only. It also added additional requirements for IM’s and text messaging.
Mobile/Portable/Wireless and Removable Storage Media and Device Security

Policy: All VA employees, contractors, business partners, and any person who has access to and stores VA sensitive information must have permission from a supervisor and ISO to use removable storage media/devices to store sensitive information.

In order to ensure the protection of sensitive information, all removable storage devices that connect to VA's resources via USB ports (i.e. thumb drives, MP3 Players – iPods, Zunes, and external hard drives) must be encrypted with FIPS 140-2 certified encryption. Similarly storage media such as CDs/DVDs that contain VA sensitive information must be adequately protected with FIPS 140-2 certified encryption.

All Department staff who has access to and stores VA sensitive information must have written approval from their respective VA supervisor and ISO before sensitive information can be removed from VA facilities/operating units.

VA sensitive information, to include all sensitive information entrusted to VA, must be in a VA protected environment at all times, or it must be encrypted. OI&T must approve the protective conditions being employed.

Utilization of personally-owned USB thumb drives within the Department is prohibited. If the need to utilize a thumb drive as an external storage device exists. This must be approved by the individual's supervisor and the thumb drive must be provided by the local OI&T senior representative.

The procurement of thumb drives will be accomplished under the direction and control of OI&T. Investigators requesting encrypted thumb drives must send their request via the Research Office

VA employees are not authorized to access or store any VA information using a thumb drive that has not been procured and issued by OI&T and they must have written permission to receive and use a VA issued thumb drive.

Non-VA personnel (contractors, business partners, etc.) supporting VA must furnish their own FIPS 140-2 certified USB thumb drives that conform to the published listing of VA approved USB thumb drives. Further, permission must be obtained from a designated VA supervisor before they can be utilized.

The listing of VA approved USB thumb drive is derived from NIST FIPS 140-2, Validation Lists for Cryptographic Modules. This listing can be found on the Information Assurance Web Portal. The link to this portal can be found on the VA Intranet, Office of Information and Technology home page.

VA sensitive information may not reside on other non-VA owned Other Equipment (OE) unless specifically designated and approved in advance by the appropriate VA official (supervisor), and a waiver has been issued by the VA’s Chief Information Officer (CIO). The non-VA systems or devices must conform to, or exceed, applicable VA security policies or are specifically authorized by official VA policy. Users of remote systems must follow all policies and procedures outlined in this policy. The local OI&T Chief /CIO and supervisors will authorize the use of portable, mobile and wireless devices within their operating unit.

Two-factor authentication, (where one of the factors is provided by a device separate from the computer gaining access) is required for remote access to VA systems.

All remote systems (VAGFE and OE) must be equipped with, and use, a VA-approved antivirus (AV) software and a personal (host-based or enclave based) firewall that is configured with a VA-approved configuration. Software must be kept current, including all critical updates and patches. The local facility OI&T office will provide and maintain the software for VAGFE. Users of waivered OE are responsible for providing and maintaining the anti-viral software and the firewall on the non-VA owned OE.
All devices used to transmit and store VA information outside of VA’s protected environment must use FIPS 140-2 approved encryption. This includes laptops and thumb drives and other removable storage devices.

Mobile and portable systems will be stored securely when not in use. Supervisors must ensure users understand their responsibility to securely store all portable systems such as laptop computers, notebook computers, PDA’s, handheld devices, wireless telephones and removable storage media devices when they are not in use and whenever they are in an unsecured environment.

A mobile storage device must not contain the only copy of sensitive information. A back-up of the device must be created at regular intervals and stored securely.

VA employees, contractors, subcontractors, and volunteers must immediately report to his or her VA supervisor and the local ISO any incident of theft, loss, or compromise of any VA sensitive information, VA equipment or device, or any non-VA equipment or device used to transport, access, or store VA information. The ISO will promptly report the incident (within one hour) to the VA-NSOC in accordance with the OI&T Incident Management procedures.

Portable and mobile devices (e.g., notebook computers, workstations, personal digital assistants) are not allowed access to any VA network without first meeting the VA’s and the facility’s security policies, procedures, and configuration standards. These include scanning the devices for malicious code, updating virus protection software, scanning for critical software updates and patches, conducting primary operating system (and possibly other resident software) integrity checks, and disabling unnecessary hardware (e.g., wireless).

Mobile, portable and wireless devices will follow VA policy regarding system hardware and electronic media sanitization and disposal.

Wireless devices can pose a significant security risk to the VA due in part to unique vulnerabilities of the wireless extensions to the network located outside of the physical confines of the controlled area. To minimize the risk, the following measures shall be implemented.

FIPS 140-2 Encryption of information transmitted to and from a wireless device is required or an appropriate waiver has been approved by the CIO.

Wireless devices must meet and be kept up-to-date on the latest anti-viral and software/security patch remediation, as applicable.

Authentication is required to protect wireless access to the information system.
VA Informatics and Computing Infrastructure (VINCI)

The VA Informatics and Computing Infrastructure (VINCI) is a centralized data repository that serves as a common point of entry for approved VA and affiliated investigators with both human subjects and VA Virtual Private Network (VPN) approval. Data available on VINCI include the Corporate Data Warehouse (CDW), Medical SAS Data Sets, DSS NDEs, VSSC, DSS Web Reports, and Vital Status Files. Descriptions of available data can be found on the VA Intranet at: http://vaww.vinci.med.va.gov/vincicentral/Data.html.

Through VINCI there are opportunities to coordinate use of multiple data sources using available tools for data processing, analysis, reporting, and natural language processing (extracting information from text). Following VINCI project approval, VA researchers and their colleagues access VINCI through a secure, virtual working environment using a certified VHA network computer, or through an approved VPN and remote desktop application. The data and the desired applications used to analyze the data are found in this remote computing environment. The data analysis is done directly on VINCI-CDW on servers located at the Austin Information Technology Center. Using this central, secure location ensures that no data are transmitted to local PC hard drives. Researchers can bring their own data sets to VINCI, as long as they have approved Data Use Agreements and/or IRB approvals.
Safe Access File Exchange (SAFE)

A new, SAFE way to send files. Need to electronically send or receive large files, but need to avoid unsecure transmission methods? The Safe Access File Exchange (SAFE)* is now available for use by VA personnel.

Provided by the U.S. Army Aviation and Missile Research, Development, and Engineering Center (AMRDEC), SAFE is a web-based product that enables VA employees and contractors with active PIV cards to securely send or receive large ( < 2GB) files to and from individuals with a valid .gov, .mil, .com, or .edu email address.

Is it secure?
The files passing through the system are automatically scanned for viruses and marked for retrieval by the recipient, who will receive a private email with a link, and a one-time password to retrieve the file. Files have a 14-day restriction before they are automatically deleted.

What are the rules for use?
SAFE is only for official U.S. Government-related business.
Works with a valid DoD Common Access Card or VA PIV card.
All files transferred must be UNCLASSIFIED.
SAFE is not intended to send information to Veteran patients.
Sending or receiving files from unfriendly countries will be monitored and blocked.

How can I use it?
2. Choose the Click Here for CAC Users option (left side), choose your email certificate, and enter your PIV PIN when prompted.
3. Complete the Personal Information section, name, and email.
4. Click the Browse button to select the file to upload. Total size cannot exceed 2GB. Add a description of the file.
5. Add a recipient email address in the Recipient Information section.
6. Next check the following Email Settings.
   - Check the box to turn on encryption (and Privacy Act Data).
   - Require CAC for Pick-up.
7. Finally click UPLOAD to begin the transfer. Click “I Agree to the SAFE Usage Policy” and leave your browser open until the upload has completed.
8. You will receive a message in your browser and a confirmation email indicating the files were successfully uploaded.
9. The recipient will receive an email with instructions for accessing the file.


*While using SAFE, please ensure recipients either have a need for the information in the performance of their official VA duties or that privacy legal authority exists to disclose the information to the recipient. SAFE adheres to all guidelines in the VA Handbook 6500, which outlines VA privacy and security policies regarding the transmission of sensitive and private data.
Reporting Security Breaches

Employees are responsible for reporting suspected or identified information security incidents (security and privacy) the Operating Unit’s Information Security Officer (ISO), Privacy Officer (PO), and their supervisor as appropriate.

Employees are required to secure VA sensitive information in all areas (at work and remotely) and in any form (e.g. digital, paper etc.), to include mobile media and devices that contain sensitive information, and follow the mandate that all VA sensitive information must be in a protected environment at all times or it must be encrypted (using FIPS 140-2 approved encryption).

Employees will properly dispose of VA sensitive information, either in hardcopy, softcopy or electronic format, in accordance with VA policy and procedures.

Employees will not leave their computers unattended. Computer are to be locked when employees are not at their computers.

General computer questions should be directed to the VISN help desk by dialing 14 and requesting assistance.
# Records Retention Schedule

National Archives and Records Administration (NARA) is given, all original research records must be retained indefinitely. Dr. Sharon Saivar ([Sharon.Saivar@va.gov](mailto:Sharon.Saivar@va.gov)) is the Records Control liaison for Research Service. She should be contacted for records retention question for research records.

<table>
<thead>
<tr>
<th>Records Schedule #</th>
<th>File Type</th>
<th>Description of Files</th>
<th>Destruction Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td>Doc of Required Res Activities</td>
<td>Research Project files and Cooperative Research and Development Agreements (CRADAs).</td>
<td>6 years after cut-off or longer</td>
</tr>
<tr>
<td>7.2</td>
<td>Research Accreditation</td>
<td>Any records concerning research accreditation</td>
<td>2 years after cut-off</td>
</tr>
<tr>
<td>7.3</td>
<td>Research Publications</td>
<td>Copies of publications resulting from funded and approved research activities.</td>
<td>6 years after cut-off</td>
</tr>
<tr>
<td>7.4</td>
<td>VMU Files</td>
<td>All VMU records</td>
<td>3 years after cut-off</td>
</tr>
<tr>
<td>7.5</td>
<td>Biosafety/ Biosecurity Program Files</td>
<td>Records related to research laboratory inspections, emergency response planning, information on chemicals or other hazardous substances, etc.</td>
<td>3 years after cut-off</td>
</tr>
<tr>
<td>7.6</td>
<td>Research Investigator Files</td>
<td>Everything and anything that pertains to the research study The investigator is not the grantee, nor does the investigator own the data.</td>
<td>6 years after cut-off, if drug or device study 2 years after approved marketing</td>
</tr>
<tr>
<td>7.7.1</td>
<td>Protocols Approved by the Committee or Subcommittee</td>
<td>Protocols Approved by the Committee or Subcommittee</td>
<td>6 years after cut-off, if drug or device study 2 years after approved marketing</td>
</tr>
<tr>
<td>7.7.2</td>
<td>Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator</td>
<td>Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator</td>
<td>3 years after cut-off</td>
</tr>
<tr>
<td>7.8.1</td>
<td>Implementation Records</td>
<td>Records that are not listed anywhere else in this schedule.</td>
<td>3 years after cut-off</td>
</tr>
<tr>
<td>7.8.2</td>
<td>R&amp;D &amp; Subcommittees</td>
<td>Records include, but are not limited to, membership rosters, appointment letters, curricula vitae, training records, meeting minutes and related documentation.</td>
<td>6 years after cut-off</td>
</tr>
</tbody>
</table>

- *Cut-off is the end of the fiscal year*
PROCESS FOR AUTHORIZED TRAVEL

All employees must request approval through their supervisor/service chief. The service chief is required to obtain approval through their respective ELT, who will then request approval through the Director. The request process should be done via email.

Before Travel – Submit travel request via LEAF (Electronica Version of SF-182)
Travel/Tuition request in LEAF (Light Electronic Action Framework) web site:
https://vhav05webrm.v05.med.va.gov/VISN22/691/finance/

In the LEAF request, travelers must justify travel and attach all necessary information regarding the travel and/or training such as Information to the Traveler (ITT), training brochure, and so forth. Once the request is submitted in LEAF, the request will be routed all the way from direct line supervisor to Executive Leadership Team.

Once approved in LEAF, please TAKE A SCREEN SHOT OF THE LEAF PAGE showing that you are approved in LEAF and save it as JPEG or PDF. You MUST ATTACH THE SCREEN SHOT TO AUTHORIZATION in CGE Concur.

Expenses requiring pre-approval from Financial MGMT or Executive Leadership

Pre-approval before travel is required for the following expenses:

Expenses that can be requested in LEAF:

Car rentals – Travelers must justify why car rental is more cost effective than public transportation.

Private own vehicle use: - You must go through the transportation share point to request for a Gov’t vehicle first: http://vaww.portal.gla.med.va.gov/sites/FacMgmtNew/Eng/trans/default.aspx If the request is approved, and you use the Gov’t vehicle, there will be no reimbursement on mileage

If there is no Gov’t vehicle available during the time of travel, you will be reimbursed for the mileage driving your own vehicle (54.5 cents per mile). Motorcycle (51.5 cents)

If there is a Gov’t vehicle available and you still decide to use your own vehicle, the rate will be 18 cents per mile.

If you want to drive your own vehicle to a TDY location where flying is the most economical, you will need to do cost comparison between the round-trip flight cost from home to the TDY location and the mileage reimbursement from home to the TDY location using VA Form 10079. And, the form should be attached to Travel authorization in CGE Concur. Please contact Travel Office for the cost comparison form (VA Form 10079).

Expenses that should be requested through Travel Office:

Hotel/Flight internet connection use
Special Accommodation - REQUESTING OTHER-THAN- COACH-CLASS - (OTC)
• Traveler must fill out VA Form 0899. Please refer to VA Financial Policy XIV Ch. 3, Appendix C for additional information: https://www.va.gov/finance/docs/VA-FinancialPolicyVolumeXIVChapter03.pdf

Hotel rate over Per Diem rate - Traveler will justify why it is an extenuating circumstance that the traveler must book the hotel.
Make reservation and submit Travel Authorization in CGE Concur. Once the Travel LEAF request is approved, and your CGE Concur account is set up, you can start making a reservation for flight and/or hotel, and create & submit a Travel Authorization in CGE Concur website.

https://cge.concursolutions.com

Travelers must go through CGE Concur to book flight and hotel accommodations.

Exception:

When there are a block of rooms set aside for Gov’t Per Diem rate, travelers can book with hotel straight. However, travelers booking outside CGE Concur should subsequently enter the hotel info in CGE Concur. Full time board certified doctors travelling for CGE ($1,000 per year) can book outside.

Before you submit your request, confirm the accounting information (Line of Accounting) with your Supervisor, your Administrative Officer, Budget, and/or Travel Office.

After Travel

Travel Authorization in CGE Concur (https://cge.concursolutions.com/)

Complete your Voucher in CGE Concur within 5 days after you return from your trip.

Scan receipts for lodging and any additional expenses (taxis/shuttles, baggage fees, etc.) and email to yourself as a PDF.

Meal receipts are not required.

Receipts are required for the following expenses, regardless of amount:
1. Authorized excess baggage (exceeding weight, size or number of pieces carried free by the carrier); 1 checked in bag for 1 week, 2 for 2, and so forth
   - Common Carrier Transportation (e.g. flight, train, and so forth)
   - Final ticketed flight invoice from Duluth, Travel Agency - When you book a flight in CGE Concur and the travel authorization is posted, you will receive an email from Duluth. From the email, there is a link to the Duluth website where you can get the flight invoice in PDF.
   - 3. Dry-cleaning and laundry (at least 6 consecutive nights of lodging) – However, a receipt is not required for coin-operated dry-cleaning and laundry machines.
   - Foreign travel expenses
   - Lodging
   - Professional administrative expenses (e.g. computer, printers, fax, and so forth)
   - Rental Car
   - Travelers will not be reimbursed for costs over the government per diem rate. Anything over per diem will be at travelers’ own expense. Travelers must receive pre-approval before travel to receive full reimbursement for the lodging over Per Diem rate.
   - Gratuity and service tips for transportation (e.g. Taxi and Shuttle) will only be reimbursed up to 15%. Anything over 15% will be at travelers’ own expense.
   - Upper MGMT made a decision that our station will reimburse up to $12 per day for airport parking. Anything over $12 will be at travelers’ own expense.

Personal time in conjunction with Official Travel When a GLA traveler wants to have a personal time in conjunction with official travel, the traveler must do Cost Comparison using the VA Form 10079A. And, attach the form to Travel Authorization in CGE Concur. Please contact Travel Office for additional information.
**Cross Funded Travel**

A. If your travel is being funded by another VAMC, i. Ensure you obtain the correct Cross-Funding Organization and Line of Accounting information. Ensure you select the correct Cross-Funding Organization as you make a reservation in CGE Concur or as you create a Travel Authorization and a voucher.

B. If our station (Station 691) is funding a travel for an employee from another station, the service inviting the employee, or paying for the travel expenses, should submit the travel request in the share point for the employee. Once the travel SharePoint is approved, the service needs to contact Travel Office for Station 691 cross funding information so that the service could provide the information to the employee.

**Donated Travel**

*It is recommended that travel using donated funds be initiated 4 weeks in advance.

A. Travel using funds from a non-federal source is considered donated. Donated travel requires an additional step. The traveler must complete the VA form 0893, which is forwarded to multiple approving officials.

B. VA form 0893 will be submitted to GLA Travel Group. Attach a brochure, link, or any information that pertains

C. Once a fully signed/approved VA form 0893 is received, the traveler must go through Travel SharePoint & CGE Concur (Sponsor / Non-Fed Sponsor (Donated) Travel).

**International Travel**

A. International travel requires that you obtain an official government passport – separate from the personal passport you may have.

B. Foreign Travel Packets must be submitted at least **60 days prior** to international travel.

C. Contact Travel office, or see International Travel Guide for additional guidance and forms.
R&D TRAVEL AWARD POLICY

1) The travel allocation is an “Award”. This would make it an item to be included on the person’s CV.

2) The Scope of the Award includes all GLA sites: WLA, Sepulveda, and any other of the GLA sites having research.

3) The award eligibility is limited to Merit Review and Career Development Award recipients.

4) The award amount is limited to $1,000 per person

5) Each year, requests from eligible investigators are received in September. The R&D Committee selects awardees up to the amount available in the fiscal year’s travel funds.

6) Recommended selection criteria includes:
   a) VA funding level, with the less well-funded persons having a higher funding priority.
   b) Level of productivity, with a higher level of productivity (research projects, publications, presentations, etc.) having a higher priority.
   c) Extent of VA community service, with a higher level of involvement having a higher priority.

7) Awardees are ineligible for future funding until all other potential awardees have had an opportunity to apply.
KEY POLICY AND SECURITY SYSTEM  
TO RESEARCH BUILDINGS  

General Information

Keys will be issued upon request only to Research Service staff who are VA paid employees. Volunteers and WOC’s will not be issued keys directly from the Locksmith. However, at the discretion of the Principal Investigator, keys may be given to volunteers and WOC’s as needed but with the understanding that the Principal Investigator is responsible for the return of the key, cost of lost keys, and any problems associated with entry of a volunteer into keyed areas.

West Los Angeles Facilities

Keys for the PI’s laboratory area should be requested through Jerry Dungan, Research Biosafety Officer, building, 114, room 326a, Ext 41303.

Key requests for common areas, such as the Veterinary Medical Unit, must first be approved by the VMU Facilities Manager, or by the Administrative Officer, Research Service for other common areas in Research Service. In any of those situations, the request for the key(s) must come from the VA Paid employee who will sign for and be responsible for the key(s) and who must list each of the non-VA paid employees they will be transfer the keys to. When the volunteer or WOC’s leaves station, the keys that were assigned to them must be returned to the person who originally signed for them.

Engineering Service will notify the person who will be responsible for the keys, via email, when the keys are ready for pick up at building, 63. Only that person will be able to sign out those keys. In most cases, the responsible person is the PI. Remember, the originator is responsible for the key that he/she requests and picks up. Any lost keys are charged at $5.00 for replacement; keys must be turned in to the lock shop upon termination of employment at GLA.

Entrances to buildings 113, 114, and 115 are to be locked at all times. The entrance doorways are automatically locked and require an authorized keycard for entrance. Investigators requiring keycards for themselves or their employees should request these from Research Biosafety Officer who will first confirm employment status either as VA-paid or WOC and then authorize issuance a keycard. The Research Biosafety Officer will program all cards for entry to specific Buildings depending on where the employee’s laboratory is located. Cardholders are responsible for lost or stolen cards and the attendant replacement fees.

Sepulveda Facilities

Employees at Sepulveda may place their key requests through Maureen McCorkle, Secretary, building 1, room C108. If the person requesting the keys is a VA employee, they can sign for the keys when the locksmith makes the key(s). If the employee is a WOC employee, the Principal Investigator must sign for the keys. The employee should call the locksmith after a couple of days to ensure the locksmith has received the work order. If the keys are ready the employee can go to the lock shop and sign for the keys.
PERSONNEL IDENTIFICATION BADGES AND VEHICLE REGISTRATION

Personnel Identification Badges

Once authorization for employment as paid VA staff or Without Compensation (pay from other than the VA) or authorization as a volunteer is given by Human Resources, Human Resource will provide ID Badges for the employee or WOC. A PIV Identification card are issued at building 218, room 1.

PLEASE make a note of the expiration date on your PIV badge. You will NOT be notified when your expiration date is coming near. New badges are required every 3 years for career employees. WOC badges expire when their WOC appointment expires. This is a lengthy process and you should contact Jason Binning (x49401) at least 2 months in advance of the expiration date.

The PIV badge that includes a microchip containing identifying information is the only VA badge that is provided to staff.

VA badges are required to be worn at all times while on the VA campus or when conducting VA business. Badges are acquired through HR/VA Police and are initiated as part of the hiring process (this includes WOCs, IPAs, and some contractors if they are working on station).

The PIV badge is required for staff to use their computers. If you lose your badge, or it has expired, your supervisor must be notified ASAP so a new one can be issued.

Vehicle Registration

Additionally, the employee, volunteer, or WOC may register his/her private vehicle with the VA Police and receive a vehicle identification sticker that will enable the authorized parking of vehicles on VA grounds.

Parking in lots around the research buildings on the north side of the West Los Angeles campus and at Sepulveda in general does not require entry into a gated lot. Parking lot 17 just south of building, 114 is a gated lot for Research and a card key for that lot may be obtained from Linda Caffey, Secretary, building 114, room 330 or Jerry Dungan, Research Biosafety Officer.
HUMAN RESOURCES

Type of Employment Appointments Offered in Research Service

General Information: All persons who work in or are affiliated in some way with the VA research enterprise must have some type of VA appointment. The types of appointments appropriate for participation in Research are:

- VA-paid Appointments
- Without Compensation Appointments (WOC, pronounced like “walk”)

There is a third type of appointment that is facilitated through an Intergovernmental Personnel Agreement (IPA), but at VA Greater Los Angeles (GLA), we require a WOC appointment prior to the initiation of an IPA.

VA Appointments

VA-paid appointments are governed by authorities detailed in regulations overseen by the Office of Personnel Management (OPM), which is a separate administrative organization than the VA. OPM regulations apply to all Federal agencies. For the VA, the applicable authorities are:

- Title 38 - Primarily direct patient-care responsibilities (doctors, nurses, etc.)
- Title 38 hybrid - Special cases (audiologists, nuclear med techs)
- Title 5 – everybody else

Title 38 employees are primarily hired through the Medical Center, and it is rare that Research Service would utilize this hiring authority. The same is true of the Title 38 hybrid category although again, there are exceptions. Thus, most of our VA hires fall under Title 5.

VA Appointments of short duration (one year or less)

Special Needs – This type of appointment is used when making temporary limited appointments for a maximum of two months. No more than one appointment of a given person may be made during any period of 12 consecutive months. These appointments are non-competitive. Persons appointed do not receive leave, health or life insurance benefits.

- Special Needs (30/30)
  - 30 days, may be extended additional 30 days
  - No Benefits

Excepted – This temporary appointment should be used if your funds or workload are not sufficient to cover employees after 1 year or if the remaining length of your project is less than 1 year. These are non-competitive appointments. No more than 1 appointment of a given person may be made. Persons initially appointed for more than 90 days are eligible for annual and sick leave; they do not receive health or life insurance benefits.

- Excepted (limited job titles)
  - Up to 1 year
  - Health Techs, Medical Instrument Techs, Psych Techs, Therapy Assistants.
  - No Benefits

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VA-Paid Appointments of Longer Than One Year Duration

**Term** – Term appointments are the most commonly used in Research. This appointment lasts between 1-4 years, is of a 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 one term appointment must compete for another term appointment. Individuals initially appointed for 366 days or more are eligible for annual and sick leave and health and life insurance benefits. We can reappoint for up to 4 years without competition, but the position must be re-competed at the end of every 4 year term.

**Schedule B** – This appointment is used for scientific, professional, and technical positions grade 11 and above when funding is guaranteed for over 4 years and may be made for any period of time up to but not exceeding 7 years. An example of a Schedule B appointment would be an individual who has completed a PhD requirement but has only limited experience as a lead investigator in a major medical research project. Persons initially appointed for 13 months or more are eligible for annual and sick leave, and health and life insurance benefits.

**Schedule A (q) Student appointments** - This is for positions at grade GS 7 and below when appointees are to assist scientific, professional, or technical employees. Persons employed under this provision must be: 1) bona fide high school science or mathematics teachers or 2) bona fide students at high schools or accredited colleges or universities who are pursuing courses related to the field in which employed. The appointment of any individual under this authority terminates upon the individual’s ceasing to be enrolled in a qualifying educational program or to be employed as a teacher. No person can be employed under this provision in 1) positions of a routine clerical type or 2) positions in excess of 1040 working hours a year, except that the working hours a year limitation does not apply to positions at GS-4 and below. For this appointment the following information is mandatory:
   1. Each quarter or semester, proof of current enrollment in an accredited school.
   2. Course listing for each quarter or semester.
   3. If the student has in excess of 120 semester hours, a letter from the school stating the individual does not have a 4-year degree.

**Schedule A (u) -** Positions when filled by severely handicapped persons 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.

**Schedule A** – appointments are non-competitive appointments. Both Schedule A (q) and (u) employees will be eligible for annual and sick leave and health and life insurance if their initial appointment is for 13 months or longer.

**Career** – These are employees who have permanent employment status in the Medical Center. Research Service cannot consider hiring new employees in a CAREER status in individual research programs.
Step Increases

For employees with a scheduled tour of duty, the required waiting periods established by law for advancement to the next higher step are as follows:

<table>
<thead>
<tr>
<th>Advancement from...</th>
<th>Requires...</th>
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<tbody>
<tr>
<td>Step 1 to Step 2</td>
<td>52 weeks of creditable service in Step 1</td>
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<tr>
<td>Step 2 to Step 3</td>
<td>52 weeks of creditable service in Step 2</td>
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<tr>
<td>Step 3 to Step 4</td>
<td>52 weeks of creditable service in Step 3</td>
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<tr>
<td>Step 4 to Step 5</td>
<td>104 weeks of creditable service in Step 4</td>
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<td>Step 5 to Step 6</td>
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<td>Step 6 to Step 7</td>
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<td>Step 7 to Step 8</td>
<td>156 weeks of creditable service in Step 7</td>
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<tr>
<td>Step 8 to Step 9</td>
<td>156 weeks of creditable service in Step 8</td>
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<tr>
<td>Step 9 to Step 10</td>
<td>156 weeks of creditable service in Step 9</td>
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Performance Appraisals:

Performance Appraisals (PA) are conducted three times per year.

1. At the beginning of the new fiscal year (October 1); PIs (supervisors) are required to meet with their employee(s) and perform an overview of duties/responsibilities. The front of the performance appraisal is required to be signed by the PI and the employee.

2. At the 6-month mark; progress review is performed with the employee. At this meeting, you should be conveying to the employee what duties that they are performing outstanding and/or what duties they are underperforming.

3. At the end of the fiscal year (September 30); the annual performance review is completed. Before meeting with your employee encourage your employee to do self-evaluation and give it to you prior to meeting for the annual performance meeting. At this meeting, you need to discuss their annual performance, if they did a self-evaluation respond the employees’ evaluation. After meeting the employee sign the appraisal and give a copy of the appraisal to the employee. Once the employee is given a copy of their evaluation the employee needs to sign on the bottom of the last page of the review.

If an employee is promoted or changes positions during the fiscal year, you will need to have a close out performance appraisal for the old position and review the duties of the new position.

If an employee leaves your section and moves on to another department you will need to have a close out performance appraisal.

Once the appraisal has been completed for the rating year the appraisal form should be sent to the Research Administrative Office.
Without Compensation Employees (WOC)

WOCs are persons working at the VA facility but whose salary comes from the University or VA non-profits, or other independent funding. A WOC appointment allows these people to legally work at the VA facility and in cases of emergencies such as injury or sickness related to their work, would entitle them to emergency medical care at the VA.

A WOC application packet is normally obtained at WOC orientation. These orientation sessions are held on Tuesday at West LA, and on Friday at Sepulveda. It is best to call or email ahead to register for the orientation. Some accommodations can be made for individuals that are not able to attend one of the orientation sessions on a limited basis. Completed WOC paperwork should be returned to the Research Personnel Manager for processing. Only complete packets will be accepted. The rationale for this is that we have many personnel transactions going at any given time, and when individual documents are returned, the opportunity to lose the material increases dramatically. For this reason, packets should be returned by the individual to whom the packet applies, and it is expected that all materials are included with the submission.

WOC employees will be asked to register with Employee Health (Administrative Medicine) in Bldg 304, 1st floor. As required of any VA employee, proof of tuberculosis status must be confirmed by either written statement from the WOC’s employment base (University, VA-non-profits, or other), or by receiving testing from Employee Health at no cost to the WOC. Additionally, for those WOCs who may be involved in research utilizing blood or other body fluids, hepatitis B vaccine is offered without charge.

These packets will then be forwarded to Human Resources. After appropriate review and signature by the Chief of Human Resources, confirmation in the form of a signed approval form for WOC appointment is returned to our Research Personnel Section. The Research Personnel staff will then notify the appropriate sections of the University or VA non-profits that approval of WOC status has been achieved. At that time the WOC employee will need to schedule an appointment through the Research Personnel Section to secure a badge from Human Resources, building 218, room 1. WOC can obtain an appropriate parking sticker for his/her vehicle from the Police Station, building 236, and appointment is not necessary.

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

Intergovernmental Agency Personnel Agreements (IPA) –

The Intergovernmental Personnel Act and the provisions of this act are set forth in 5 CFR part 334. The act allows for “mobility assignment” of a person with specific skills that 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 these skills. The act was created in order to facilitate benefit to both the “sending” and “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 (i.e., the VA). It should be noted that an IPA is NOT a funding mechanism for personnel. This is a common misconception. It is a mechanism for reimbursing one agency for work performed at another. If sufficient funds for a position do not exist at the sending agency to cover the assignee, then an IPA should not be used to pay the assignees salary. An IPA is a contract and provides for reimbursement to the sending agency for work performed by the receiving agency by the assignee. For this reason, the employees signs that contract, meaning that they are willing to be assigned under the terms of the contract; the employing or sending agency signs that they are willing to send the employee and continue to pay them at their normal salary rate, and the receiving agency signs indicating that they will reimburse the sending agency at the rates set forth in the contract.
Time limitations for assignment: The VA has been exempted from the time limitations for the duration of mobility assignment. Prior to waiving of this limitation which still exists for other federal agencies, the limitation of mobility assignment was 2 years, but could be extended for up to 6 years with appropriate breaks in service after 2 and 4 years.

The IPA provides for a broad spectrum of skills that can be placed on mobility assignment. The keywords of interest that determine eligibility are that the applicable skills and or expertise must be scientific or technical. The assignee candidate must have worked for the “sending” agency for at least 3 months in a position that is considered permanent, not temporary. This designation varies from agency to agency, and should be confirmed with that agency’s Human Resources department before requesting a mobility assignment. IPA assignments should not be used as a means to overcome standard hiring practices, and for this reason positions that are primarily administrative should not be filled using mobility assignment. Students, including graduate students, are not eligible for mobility assignment.

For more information, go to:  http://www.opm.gov/programs/ipa/Mobility.asp

Instructions for Requesting an IPA Assignment

If you wish to request an IPA assignment, please complete the attached forms and submit them by email to a Personnel Manager in Research Office at least 60 days prior to the anticipated beginning of the IPA assignment. PIs should send the applications to Jason Binning at jason.binning@med.va.gov. If extenuating circumstances prevent timely submission of the request, an exception must be obtained from the Health Science Officer prior to processing of the application. Three documents are required for to request an IPA assignment:

1. An IPA Worksheet
2. A Cost Summary
3. A current Curriculum Vitae (CV) for the candidate for assignment

In addition, the assignee must have a current WOC appointment with Research Service before the assignment begins.

IPA Worksheet: The PI or designee should complete the form detailing the Purpose of the IPA, the duties that will be performed by the incumbent, and a description of the project or program that the incumbent will be working on. Specific instructions are on the Worksheet.

Cost Summary: A fund manager or personnel manager from the assigning agency (the place where the candidate is currently working) should complete the Cost Summary sheet (Excel spreadsheet). The cost summary sheet should be given to an approving official in the Research Budget office to insure that sufficient funds are available to support the assignment.

Curriculum Vitae (CV): The CV should be prepared by the candidate and submitted by the PI along with the Cost Summary and IPA worksheet.

The IPA Process

Upon submission of the completed documents, the following will occur.

1) The Personnel Manager will review and print the submitted documents. If changes are required, the PI will be notified.
2) The Cost Summary is routed to the Supervisory Budget Analyst for review and approval. The Budget Office with forward the recommendation to the Health Science Officer.
3) Upon approval of the Cost Summary, the HS Officer or designee will prepare the IPA contract for signature using the information provided on the Worksheet.
4) The completed contract will be prepared in duplicate. The candidate for assignment will be asked to sign both copies.
5) A packet is assembled to include the Worksheet, CV, and Cost Summary, and Analysis documents and routed to VA Human Resources Management Service.
6) An HRMS Specialist completes an analysis of the contract and supporting documentation and either recommends approval or disapproval and forwards the analysis and recommendation for signature to the Chief, HRMS.
7) Depending on the situation, the signed documents will be routed to the Contracts and Grants specialist at the “sending” agency for approval, or through the VA chain of command for signature.
8) Whichever routing option is initiated, the other involved agency is sent the partially signed documents for review and approval.
9) Fully signed contracts are returned to Research Service, who in turn distributes originals to the assigning agency (sending) and the receiving agency (HRMS). Copies are distributed to the assignee, and the Research Budget Office. A copy of the agreement is also kept in the Research Personnel Office.
10) The Research Budget Office establishes a purchasing obligation in the PI’s account and billing information is sent to the assigning agency for reimbursement.
11) The IPA assignment begins.
12) Billing for each performance period is determined by agency policy or agreement. Billings should be faxed to the Austin Payment Center per instructions provided by Contracting.

**WOC Clearance**

Research Service has assumed responsibility for oversight of the clearance processes which have been streamlined to minimize the time and effort required of departing WOC employees while assuring that their termination of appointment at the VA is documented and appropriate offices are notified.

The following actions must be completed prior to the departure of a WOC employee whose GLA appointment is terminated for any reason:

**WOC Employees are responsible for:**

1) Informing the Principal Investigator of their date of resignation
2) Completing the exit process which includes:
   • Completion of their portion of the Information and Security Exit Certification Form (Attachment A) with their Principal Investigator
   • Completion of their portion of the Research Service WOC Clearance Form (Attachment B) upon the turn-in of the items in the Clearance Form

**Principal Investigators are responsible for:**

1) Assuring by signature their completion of the requirements as stated in the following two forms
   • Information Security Exit Certification Form (Appendix C)
   • Research Service WOC Clearance Form (Appendix C)
2) Informing any departing WOC employee under their supervision of the WOC’s responsibility to:
   • complete their portion of these two forms
   • return both signed forms with their VA ID badge and security key cards to the Research Service administrative office (at WLA or Sepulveda)
Research Service administrative office will be responsible for:

1) Returning VA ID badges to HRMS background and security office, security key cards to Research Biosafety Officer, Information Security Exit Certification to ISO, and keys to Engineering;
2) Notifying HRMS, ISO, IRM, Employee Health, Police and Security, Radiation Safety, all R&D compliance committees, Research Portfolio Manager, and the employing non-profit foundation that clearance has been completed;
3) Documenting employee’s termination date in RPMS and transferring employee’s record file from active to archive status.
TIME AND LEAVE PROCEDURES

The Director of the VA Greater Los Angeles Healthcare System mandates that all Time and Leave be recorded and processed through Vista. The Time and Leave program, networked throughout the VA, transmits payroll information to Austin, TX, where VA employee wages are processed and distributed. This Guideline is provided to all GLA Research and Development Principal Investigators and Supervisors for information and guidance about Time and Leave rules and procedures.

The Associate Chief of Staff, R&D (ACOS) holds the electronic approval authority for Research Time and Attendance. In compliance with responsibilities for fiscal accountability, ANY payroll expense (VA or other) for which sufficient funds are not available will not be approved. All references in this guide referring to the authorities of ACOS, R&D or PI/Supervisor for leave administration are equally applicable to anyone to whom they have delegated such authorities.

Tour of Duty

Tour of duty for full-time employees is 8 hours per day, 5 days a week. GLA hours of operation is from 8:00 AM to 4:30 PM. Tour of duty can be adjusted to fit the need of the supervisor as long as it is an 8-hour tour. A half hour for a lunch period must be included in the tour for example, if you are changing the tour to begin at 8:30 AM, then the tour of duty would be 8:30 AM to 5:00 PM.

Employees are required to begin their tour on time. If employee is more than 7 minutes then the employee should be changed 15 minutes of annual leave, if available. This does not mean that the employee can be habitually late 7 minutes every day. If an employee is habitually late the supervisor needs to counsel the employee on the importance of being on time and in the future can be discipline for excessive tardies.

Crediting Work Time/Charging Leave Time

Work and leave time is credited/charged in quarter-hour (15 minute) increments. The full quarter-hour is credited/deducted on the basis of the first 7 (seven minutes). For example, for employees eligible for overtime (OT) or compensatory time (CT), if the scheduled tour ends at 4:00 p.m., and the employee works until 4:36 p.m. (with the supervisor’s and Budget’s approval) one-half hour of overtime (OT) or compensatory time (CT) would be earned. If the employee works until 4:38 p.m., 45 minutes of OT or CT would be earned.

Submission of Timesheets

Each pay period is two weeks in length, beginning on a Sunday at 12:01 am and ending at midnight on a Saturday. Each timesheet accounts for one week of the pay period. Completed timesheets are to be signed by the employee and verified and signed by the PI. The original, signed timesheets for the current week are to be delivered to the Research Administration Office, no later than 9:00 a.m., each Wednesday. The PI/Supervisor should keep a copy of each timesheet submitted.

Anticipated work hours for Thursday through Saturday are to be recorded on the timesheet. If the actual hours worked vary from what is pre-recorded, changes are to be noted and initialed by the PI/Supervisor on the copy, which is then to be delivered to the Research Administration Office. Amended timesheets for week one of the pay period are to be submitted with the timesheet for week two. Amended timesheets for week two are to be submitted no later than 10:00 a.m. on the following Monday.

While it is possible to do a corrected electronic timecard, the need to do so should be avoided. It results in unpredictable and sometimes widely varying pay for the employee and wastes many work hours
at many levels throughout the system. **ALL HOURS SHOULD BE ACCURATELY RECORDED AND SUBMITTED DURING EACH CURRENT PAY PERIOD.**

### Processing Leave Requests

#### General Information

Recognizing that personal emergencies occasionally keep employees from being at work as scheduled, the GLA policy is to grant leave, if possible, so employees can attend to such emergencies without losing pay. But, as Research Service’s primary mission is to conduct quality studies in an efficient manner, the frequency of unscheduled absence must be limited.

Unless on approved leave, employees are responsible to report for duty, on time and as scheduled. Employees are expected to submit leave requests with enough advance notice to allow the PI/Supervisor to arrange for coverage of essential work duties. Because of differing needs in each research unit, it is left to the PI/Supervisor to establish (and enforce) attendance expectations and set a reasonable timeframe for advance leave requests for his/her employees. This may be different for employee categories within the group (i.e. M.D. or Ph.D. or program clerk, etc.).

Whenever possible, the PI/Supervisor will grant the leave request. However, the PI/Supervisor is not required to approve leave requests, particularly for those not submitted within established advance request timeframe and/or with required documentation.

Each PI/Supervisor is responsible to assure that s/he has sufficient funds available to cover all current and projected costs of his/her employee payroll expenses by monitoring his/her budget statements and projections of the costs of employees’ accumulated leave balances.

Each employee should monitor his/her available sick and annual leave. Current leave balances are listed on each employee’s Earning and Leave slip and are also available on the electronic leave request menu. Leave cannot and will not be authorized when sufficient accrued leave to cover an absence is not available. **Unless the employee requests and is granted Leave Without Pay, all absences for which sufficient leave is not available will be recorded as Absence Without Leave (AWOL).**

### Electronic Leave Requests

Beginning May 27, 2018, GLA is transferring to the Veterans Affairs Time and Attendance System (VATAS). VATAS is only available on the **VA INTRANET. All VA paid Research Service employees MUST and are REQUIRED have VA New Technology (NT) account. Any VA paid employee who does not have a VA NT access should contact the Research ADP Coordinator.**

#### Leave Request to Schedule an Absence

VA paid employees must request leave electronically, through the VATAS system for any period of absence from their regularly scheduled duty time. Most employees have access to the VATAS system in their work area. Those who do not have work area access may enter requests on any VATAS terminal or on PC’s available for this purpose in the Research Administration Offices. Training for accessing VATAS and submitting electronic leave requests is provided through IRM and the Research Service ADP Coordinator.

The PI/Supervisor is expected to respond (usually verbally) to advance annual or sick leave requests within three days of receipt of the request. If a response has not been received, the employee should remind the PI/Supervisor that s/he has a leave request pending. **If the PI/Supervisor has not responded to the request after the three days, and the request was submitted in time to meet any advance notice timelines established for the unit, the employee may consider that the leave is approved.**
Leave Request Not Approved Prior to an Absence

Calling in to request leave: When an employee is unable to report for duty as scheduled, s/he is to personally contact his/her supervisor to request leave no later than two hours after the scheduled start of the shift. Unless s/he has designated an alternate(s) for this responsibility, the PI/supervisor, is the only person authorized to grant the leave.

Denial of Call-In Leave Requests: The PI/supervisor is NOT OBLIGATED to approve call-in leave requests. S/he should, however, have a valid reason to deny such requests. The PI/supervisor must inform the employee, at the time of the call-in, if s/he has decided to deny the leave request. An employee who leaves a message on voice mail or with an employee not authorized to grant leave may not assume leave has been granted.

Examples of reasons call-in leave requests may be denied are listed below, but there may be other valid reasons, depending upon individual circumstances:

1. The workload is too heavy/time-sensitive/critical to allow for the absence.
2. Too many others in the work unit have already been granted leave for the requested time.
3. The employee has no accrued leave available.
4. The employee has been notified that s/he has an unacceptable rate of unscheduled absence.
5. The call-in is during a period of time for which the PI/Supervisor has already denied the employee leave.

Submitting the leave request: As soon as possible, upon returning to duty, the employee must submit an electronic leave request.

Documentation for sick leave (per Article 35, Section 5 A): Where an employee requests sick leave, or annual leave, or LWOP in lieu of sick leave, for periods of illness exceeding three consecutive workdays of the employee’s work schedule, the employee must make an appropriate request and may be required to furnish evidence of the need for sick leave upon return to duty.

An employee may support the request for sick leave:

1. By medical certificate from the Department’s employee health care provider or the employee’s health care provider that is administratively acceptable; or,

2. By the employee’s self-certification in instances where the illness was not treated by a health care provider. The statement will indicate why a health care provider was not seen; for example, remoteness of area, general condition of the illness, or other specific reasons. The supervisor may request clarification should the employee’s written statement not be sufficient to support the request.

Scheduled vs. Unscheduled Absence

Each PI/Supervisor should define and inform all subordinates of acceptable lengths of advance notice for leave requests. In some units and/or some job classifications, it is acceptable to submit requests three days in advance. In other units and/or job classifications, or for longer periods of leave, up to six weeks or longer advance request periods may be appropriate. The PI/Supervisor may also wish to establish specific advance notice periods for leave during holiday periods. Leave requests submitted within the advance notice timeframe(s) are scheduled absences. Requests submitted with less advance notice are unscheduled (UNS) absences. All call-in absences are unscheduled absences.

PIs/Supervisors should note “UNS” on any unscheduled absences on the employee’s timesheet, along with a brief explanation (i.e. car trouble, overslept, family emergency, etc.) The timekeeper will enter this in the comments section of the electronic timecard. Excessive unscheduled absence may be the basis for counseling and/or placing an employee on a leave restriction.
Leave Categories, Documentation Requirements and Approval Authorities

VATAS – Leave Codes

**Advanced Leave (Annual/Sick).** Under certain circumstances and with supporting documentation, the Director of Human Resources may approve advanced leave. The amount may not exceed the total amount of leave an employee is expected to accumulate during the remainder of the leave year. Consult Research Human Resources to process requests for advanced leave.

**Annual Leave (LA).** Vacation leave, not covered under any other leave category. An employee may request annual leave in lieu of sick leave if s/he has exhausted his/her accrued sick leave.

**Authorized Absence (LN).** AA is used when the employee attends a pre-approved meeting or educational event away from his/her duty station. Requests for AA must include a completed VA Travel request form, and a copy of the event brochure, registration form and event itinerary/agenda. The Research Administration Office must receive requests at least 15 days prior to domestic travel and 60 days prior to foreign travel. (Per GLA Travel Policy) PIs/Supervisors are not authorized to approve AA. NOTE: R&D Committee approval is required to use and Investigator’s General Post Funds for travel/education.

Employees are limited to 15 days AA per leave year. AA for physicians must be requested through the Chief of Staff, with concurrence of the Research and any clinical supervisor and the ACOS, R&D. All other AA must be requested through the ACOS, R&D, with concurrence of the supervisor.

Attendance at HQ/VA required meetings does not count against the 15 days per leave year allowed. However, an AA request and supporting documentation must be submitted.

Employees may use up to 40 hours of excused absence, per leave year, to attend educational events/seminars on station, during regular duty hours, without charge to leave.

**Jury Duty (LC):** Leave for jury duty is recorded on the electronic timecard as AA with a notation of “Jury Duty”. Use CL on the timesheet to distinguish jury duty from other AA. Documentation is required, but an SF-71 is not. See ‘Jury Duty’ section.

**AWOL – Absence Without Leave (KC):** AWOL is entered by the supervisor if s/he denies leave for a period of employee absence, if no proper leave request was submitted or if an employee has insufficient accrued leave to cover an absence (unless approved as LWOP). Research Administration will charge all scheduled hours not accounted for on the employee’s timesheet as AWOL. AWOL is not a disciplinary/adverse action, but may be the basis on which such action is initiated.

**Family Friendly Leave and Family Medical Leave (Act):** Leave guaranteed to employees under Federal Law. These leaves may not be disapproved.

**Family Friendly Leave (FFSL):** Employees may use up to 13 days of sick leave per leave year to care for family members/significant others, providing the sick leave balance does not fall below 80 hours. FFL is pro-rated for part-time employees. FFL is requested by memo indicating the qualifying reason, to the immediate supervisor. Supporting documentation may be required. FFL is to be noted on the employee’s timesheet and will be entered in the comment section of the electronic timecard.

**Family Medical Leave (FMLA):** Employees may be approved for up to 12 weeks of LWOP per leave year for their own medical needs or to care for family members/ significant others under FMLA. Requests and supporting documentation are to be submitted to the Director of Human Resources, through the supervisor and ACOS, R&D.

**Continuation of Pay (COP) (LU and LT):** COP is approved through Human Resources to cover absences caused by work-related injuries. It is requested on the required documentation of a work-related injury. Employees may choose to request LWOP or use their accrued AL of SL pending approval of COP. The employee and timekeeper are notified of approval/disapproval of COP. If COP is approved, the employee must request restoration of AL/SL used in the interim. LU is for day of injury and LT is for traumatic injury leave.
**LWOP – Leave Without Pay (KA):** Leave Without Pay (LWOP) may be granted when an employee has insufficient accrued leave to cover periods of absence. LWOP requires a request memo and proper supporting documentation, which includes: physician diagnosis, prognosis, expected date of return to duty; or other documentation for special circumstances. Two days of LWOP is approved by the Supervisor, ACOS, R&D, can approved additional 3 days (up to 5 days per year) or Director of Human Resources (longer than 5 days). Research Service requires ALL LWOP to be pre-approved and needs to be requested in writing using the Research LWOP memo form. (see Appendix C) The Director of Human Resources is the approving authority when LWOP is requested pending approval of a Worker’s Compensation claim.

LWOP in excess of 80 hours must be documented in the employee’s Official Personnel File on an SF-52. When an employee’s cumulative LWOP exceeds 80 hours in any leave year, the pay system will make a proportional (reduced) adjustment to the employee’s leave accrual.

*LWOP is not to be used to adjust work schedules. If a part-time work schedule is not the same from week to week, the PI/Supervisor should use the appropriate approved tour (consult the timekeeper), place the employee on an intermittent tour of duty, or adjust the work schedule using Compensatory Time.*

**Sick Leave (LS):** Sick leave in excess of three days may require medical documentation.

**Disable Veteran Leave (LDV):** Disabled Veteran leave will be available only to an eligible employee hired on or after November 5, 2016. Disabled Veteran leave is only available to employees with a service-connected disability rated at 30 percent or more, as determined by the Veterans Benefits Administration. For any eligible employee, there is a single 12-month eligibility period during which disabled Veteran leave may be used. The leave benefit expires at end of the 12-month eligibility period, and any unused leave is forfeited at that time. Unused disabled Veteran leave may not be cashed out and paid in a lump sum. Disabled Veteran leave credited to a regular full-time employee may not exceed 104 hours. Employees with part-time, seasonal, or uncommon tours of duty will be provided a proportionally equivalent amount of leave.

**Military Leave (LM):** Only military duty under military orders qualifies for Military Leave. This does not include regular, weekend guard/reserve duty. An SF-71 and a copy of the signed military orders must be submitted. Employees are allowed up to 15 days of Military Leave per leave year. There are provisions for carry-over of Military Leave. Contact Research or GLA Human Resources for further information and for instances in which an employee is called to active military duty for extended periods.

**Adoption Leave (FMLA – LS):** An employee may use all accrued sick leave for purposes relating to the adoption of a child. Employees may also request advanced sick leave up to 30 days if the situation warrants it. Requests for Adoption Leave, along with appropriate supporting documentation are to be submitted to the Director of Human Resources, through the supervisor and the ACOS, R&D, no less than two weeks prior to the anticipated leave period.

**Donor Leave (Excused Absence) (LV):** Employees are entitled to up to four hours of excused absence for the purpose of donating blood (including resting and recuperation time). Employees are entitled to up to seven days of paid leave (excused absence) each leave year to serve as a bone marrow or organ donor. Additional recovery periods must be covered with sick and/or annual leave, LWOP and/or advanced sick/annual leave.

**Compensatory Time (CT/CU)/Overtime (OT):**

**Compensatory Time Earned/Overtime must be approved, in advance, by the appropriate authority.** Please note: A supervisor cannot ask an employee if they want compensatory time. Overtime must be offered. The employee must request CT in lieu of OT.

All compensable overtime work (OT/CT) requires submission of a completed VA Form 4-1098, Request for an Authorization of Overtime. See sample VA Form 1098.
Compensatory Time Earned: An employee may be entitled to request Compensatory Time Earned in lieu of Overtime pay. Compensatory Time Earned is given in lieu of pay for hours an employee works beyond his/her regular tour hours. For part-time employees, the total of CT plus paid work hours cannot exceed the number of per pay period hours designated in the employee’s appointment.

Compensatory Time Use (CT): An employee must submit a leave request to use Compensatory Time Earned (CT). The request is for CU. Requirements for advance leave scheduling apply. CU must be used before the end of the seventh pay period following the pay period in which it is earned. CU not taken within this timeframe, because of the needs of the service, will be paid the overtime rate. If it is not taken because of personal reasons, the employee’s right to compensatory time off or its conversion to overtime pay is lost.

Overtime (OT): Any hours recorded in excess of eight (8) hours per day and/or 40 hours per week will be calculated by the VA pay program as OT/CT. For employees on an approved compressed schedule, OT/CT applies to hours worked in excess of scheduled hours. Working in excess of the scheduled hours of duty, or allowing an employee to do so, without prior permission from the appropriate approving authority, violates GLA and VA policy.

Jury Duty Procedures

The VA considers jury duty a civic responsibility. Requests for postponement should be made only in exceptional situations, such as to provide critically necessary patient care or when the employee’s services are necessary to meet important deadlines.

Upon receipt of the order to report for jury duty, the employee should immediately provide his/her supervisor with a copy of the summons. An SF-71 is not required. Duty time spent on jury duty is to be noted as CL on the employee’s timesheet. When the responsibilities of jury duty prevent an employee from completing and submitting a timesheet, the PI/Supervisor may mark the card appropriately and submit it to the Research Administration Office. The supervisor should provide the employee with a copy of any timesheet so submitted.

Employees must obtain an attendance report from the court for all hours of jury duty served. The employee should notify the Court Clerk or Jury Coordinator on the first day of service that s/he requires a weekly attendance record. Although all courts supply such records, the documentation format varies from one court to another. Generally, the certified attendance record is made available on the last day of service for each week and the final day of jury duty.

On days the employee is not required to report for jury duty, (e.g., on-call status or court is not in session) s/he is to report for work, as scheduled. If the employee is excused or released from jury duty for a portion of the day, s/he must return to work if s/he can arrive at his/her duty station and have at least two hours remaining on his/her tour of duty. Alternately, the employee may choose to arrange for leave for the remaining, non-jury duty hours.

The weekly attendance report is to be submitted with the employee’s timesheet. A final attendance report must be submitted at the completion of jury duty.

Jury Duty Payment

Jury duty payment includes a daily fee, plus mileage. When payment is received from the court, the employee is to contact the agent cashier at his/her duty station and turn in the amount of the daily fee for all days for which the employee served on jury duty on scheduled work days. The employee may keep the mileage portion of the payment.

It is important that the employee keep his/her supervisor informed regarding the expected length of jury duty.
VA Funding

VA ORD Research Services

The Merit Review Award Program is an intramural funding mechanism to support investigator-initiated research conducted by eligible VA-ORD investigators at VA medical centers or VA-approved sites. There are four Medical Research Services, Biomedical Laboratory Research and Development (BLR&D), Clinical Science Research and Development (CSR&D), Health Services Research and Development (HSR&D), and Rehabilitation Research and Development (RR&D).

Biomedical Laboratory Research & Development Service

Clinical Science Research and Development Service

BLR&D: 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. This program is BLR&D and CSR&D’s principal mechanism for funding basic, preclinical biomedical and behavioral studies, as well as clinical studies of disorders and diseases of importance to the health of Veterans. It is the goal of BLR&D and CSR&D to fund only applications that propose research that is scientifically meritorious and relevant to the health of Veterans.

Merit Review Awards are BLR&D’s principal mechanism for funding basic, preclinical biomedical and behavioral studies of disorders and diseases of importance to the health of Veterans. The BLR&D purview includes in vitro and in vivo laboratory studies on tissue cultures, animal models, and human biological samples. Proposals involving procedures for obtaining biological specimens from human subjects such as drawing blood, collecting urine, performing a buccal swab, etc., should be submitted to BLR&D.

CSR&D: conducts research that focuses on intact human beings as the unit of examination. Examples include interventional and effectiveness studies, clinical, epidemiological and technological studies.

Merit Review Awards are CSR&D’s principal mechanism for funding behavioral, epidemiological, and clinical research on disorders and diseases of importance to the health of Veterans (including complementary and alternative medicine approaches such as meditation for treatment of PTSD). The CSR&D purview includes interventional, experimental, and/or observational studies involving human subjects. Proposals involving administration of survey instruments or questionnaires, collection of medical histories from research subjects (i.e., not from existing medical records), and/or performing medical procedures (including imaging studies or surgical biopsies) or treatment regimens must be submitted to CSR&D even if some specific aims in the proposal meet the purview of BLR&D Service.

BLR&D and CSR&D Eligibility

Duration of Eligibility for Nonclinical PhDs: General acceptance into the intramural program is granted for three years. Conditional or Limited permission to submit may also be granted. If Merit Review funding has not been achieved within three years or the term specified, reapplication must be made. As long as funding continues, an investigator is considered eligible, however if Merit Review or Research Career Scientist (RCS) funding has lapsed for three years, reapplication for eligibility must be made. In addition, a person whose status has changed must reapply. This reapplication should be done prior to the change in status.
**Who may apply:** An applicant need not be a current VA employee. However, it is required that individuals accepted into the intramural program will conduct their research at the VA Medical Center, participate in the administration of the local research service, and be available for national service.

1. An applicant must be a current U.S. citizen in order to submit an application for acceptance into the Medical Research Non-Clinician Intramural Program (non-clinician eligibility). If an applicant is not a U.S. citizen, he/she should meet one of the following criteria in order to submit an application for eligibility:
   2. Have a firm date for being sworn in as a U.S. citizen and submit documentation of this.
   3. Have a current VA-paid appointment and submit an SF-52 as a proof of VA-salaried employment.
   4. This program is only for non-clinician investigators with a doctoral degree.

This program is not for clinicians. ORD defines a clinician as a licensed practitioner with a doctoral degree (MD, DO, DDS, etc.) who treats patients at a VA Medical Center (VAMC). Please refer to VHA Handbook 1202.1 for further guidance. *(NOTE: For budgetary purposes, a clinician may not request salary from Research Appropriations for the Merit Review Award. Once approved for funding, the clinician may not request budgetary adjustments to pay for salary support from Research Appropriations for the duration of the Merit Review Award.)*

**Waiver of the 5/8ths rule for clinicians:**

Clinicians must have at least a 5/8ths appointment to apply for a merit review. However, a waiver of the 5/8ths rule can be requested for clinicians. A commitment to the VA must be demonstrated in the request.

**BLR&D and CSR&D Research Career Scientist (RCS):**

BLR&D and CSR&D recognize the important contributions of non-clinician Ph.D. scientists to the Department of Veterans Affairs (VA) research program. As principal investigators of BLR&D and CSR&D research programs, they make valuable contributions to our knowledge of disorders important to the United States (U.S.) Veteran population. In addition to research efforts, however, the intramural nature of the VA research program requires that principal investigators have a primary professional commitment to VA. Scientists show this commitment by appropriately acknowledging VA employment and support, participating in committee work, directing core facilities, teaching, mentoring, supervising shared resources, and other important research-related activities. In recognition of the contributions and professional commitment to the VA, BLR&D and CSR&D support a career track for the non-clinician Ph.D. scientist.

RCS designation is awarded to established, independent investigators who have distinguished themselves through scientific achievement and contribution to the VA research program via training, mentoring junior VA scientists (clinician and non-clinician), functioning as a resource for the research community, serving on VA research or other local or national committees, directing a core facility, and collaborating with clinician scientists.

Independent non-clinician Ph.D. scientists may apply to the Merit Review program for research and salary support, once they have received permission to submit a proposal. Salary support must be requested in the budget. The Research Scientist designation is conferred on the principal investigator of a funded merit award for the term of the program and will continue as long as the scientist receives VA peer-reviewed research support. Salary support may be extended for up to 1 year following termination of research support, provided the Research Scientist continues to apply for merit award funding and provides service to VA research.
BLR&D and CSR&D Career Development Award (CDA):

The Career Development program is intended to attract, develop and retain talented researchers working in areas of particular importance to improving the health and care of our nation's Veterans. BLR&D and CSR&D Services has a rich history of supporting investigators during their early research careers who have gone on to serve as long-standing, independently funded VA scientists, Center and Research Enhancement Award Program (REAP) Directors, and research administrators such as ACOS/R, etc. The current Career Development program provides opportunities for clinician and non-clinician biomedical and clinical researchers, including biostatisticians and clinical trial lists.

The objective is to promote the professional careers of outstanding clinician scientists committed to conducting biomedical research through a mentored research training program. Implicit in all CDA applications is the understanding that the applicants plan to continue their careers within VA. At the conclusion of the award, it is anticipated that the awardee will continue to work as a VA clinician research scientist and apply for independent funding through mechanisms such as VA Merit Review or other national programs.

BLR&D and CSR&D Promotions:

Positions typically eligible for consideration are those whose primary function is scientific investigation in basic or applied research in the biological, medical, health, physical, veterinary medical, computer, social (including economics), or mathematical (including statistics) sciences; engineering; industrial design; and psychology.

Requirements:

(1) A minimum of 5/8ths time commitment to VA, evidenced by a 5/8ths VA-salaried appointment or an approved eligibility waiver (see Handbook 1200.15).

(2) A record of successful past and current VA research support or successful competition as a principal investigator for significant, extra-VA research funding from a national program that utilizes a standard of scientific merit review equivalent to that of VA, or both.

(3) Publications in peer-reviewed scientific and professional journals widely read within the nominee’s field, particularly as the first or senior author.

(4) Invitations to speak or chair sessions at national or international scientific meetings.

(5) Membership on national scientific advisory or merit review committees or editorial boards of scientific or professional journals.

(6) Recognition by peers as a leader in a research field.

(7) Interaction with clinicians, researchers, and managers in support of the patient care and research and development programs.

(8) An active role in the training of young scientists and in formal teaching.
HSR&D pursues research at the interface of health care systems, patients and health care outcomes. HSR&D underscores all aspects of VA health care; specifically, quality, access, patient outcomes and health care costs. HSR&D’s mission is to advance knowledge and promote innovations in quality, effectiveness, efficiency, cost, and accessibility of health services to improve the health and care of Veterans.

**Merit Review Awards (IIR – Investigator Initiated Research)** are HSR&D’s principal mechanism for funding studies that examine the organization, delivery, and financing of health care, from the perspectives of patients, caregivers, providers, and managers to improve the quality of healthcare. Specifically, HSR&D is interested in evaluations of the structure, processes, and outcomes of care, including issues of patient safety and equity. HSR&D also is concerned with system-level outcomes such as assessments of cost and access, as well as effective ways to translate clinical knowledge into practice. The underlying objective of health services research in VA is to understand and improve clinical decision-making and care, inform patients, evaluate changes in the health care system, and inform VA policymaking. HSR&D projects are often multidisciplinary activities. They involve expertise in a combination of clinical fields (medicine and all its specialties, nursing, and other health care professions), social sciences (especially psychology, sociology, economics, and organization theory), and multiple research approaches and methods (experimental and quasi-experimental studies, survey research, database analyses, biostatistics, psychometrics, econometrics, modeling techniques, etc.). The current HSR&D priorities for Investigator Initiated Research can be found at [http://vaww.research.va.gov/funding/solicitations/default.cfm#HSRD](http://vaww.research.va.gov/funding/solicitations/default.cfm#HSRD).

The “laboratory” for health services research studies is the real world of clinical practice, where variations among patients, physicians, and other factors that affect health care cannot be fully controlled (and may, themselves, be the focus of research). In general, studies involving treatments that are still regarded as experimental are not in the domain of health services research.

**Centers of Innovation**

HSR&D has 19 Centers of Innovation (COIN) that conduct research on an array of healthcare issues. Each COIN develops its own research agenda, is affiliated with a VA medical center, and collaborates with local schools of public health and universities.

The COIN program rewards research innovations and partnerships to ensure that research has the greatest possible impact on VHA policies, healthcare practices, and health outcomes for Veterans. A unique feature of the COINs is that they include one or more focused areas of research that addresses questions of significance to VA clinical and operational partners, and these partners will be engaged in the research activities of the COINs.

**GLA Center for the Study of Healthcare Innovation, Implementation and Policy**

The VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy (CSHIIP) has played a fundamental role in the ongoing transformation of VA health care. CSHIIP’s work is anchored in a longstanding history of partnered research that has infused our Center with a strong understanding of VA priorities. Partnerships and priorities continually guide our strategic planning, enabling us to build a portfolio of highly responsive research informing evidence-based practice and policy in key focused and emerging areas. However, major changes within and outside the VA over the past few years necessitate deployment of novel strategies to tackle the profound challenges facing the VA healthcare system. These changes, including the access crisis, shifts to community care, and increased awareness of gaps in quality for high-risk/high-need (HR/HN) Veteran patients, have augmented demand for research to address these fundamental issues, and thereby improve Veterans’ routine care experience at VA. Accordingly, CSHIIP has realigned its mission, vision, priority goals, and strategic plans to meet these new challenges.

CSHIIP’s mission is to develop and test innovative care models and health systems interventions to markedly improve the effectiveness and value of VA health care, from system, provider, and Veteran perspectives, while advancing scientific methods for accelerating adoption, implementation, spread, and scale-up of evidence-based practice. Aligned with VA strategic frameworks at the national, network,
local levels, our vision is to promote delivery of proactive, personalized, and patient-driven care that is evidence-based and continuously improving. We will leverage our 25 years of expertise in provider behavior, implementation science, and pathways to high-impact research to achieve the following priority goals:

**Goal #1:** To improve primary care delivery, with an emphasis on access, team function, and care coordination in the context of VA’s medical home model (PACT) and medical neighborhood within and outside VA;

**Goal #2:** To increase implementation, accessibility, and impacts of gender-sensitive comprehensive care for women Veterans through innovative care models and multilevel stakeholder engagement;

**Goal #3:** To improve care quality, patient experience, and outcomes among high-risk/high-need Veterans, focused on subpopulations with serious mental illness, homelessness, substance use, as well as older adults and acute care patients;

**Goal #4:** To develop, test, and implement novel care models in emerging areas, including complementary and integrative health/whole health, specialty care, and emergency management/disaster preparedness;

**Goal #5:** To recruit, train, mentor, and retain researchers in our recognized areas of expertise, including health systems interventions, implementation science, and partnered research; and

**Goal #6:** To accelerate our research impacts through strategic partnerships, Veteran and employee engagement, implementation and dissemination, and internal evaluation and communication.

To accomplish these goals, we developed a logic model anchored in learning healthcare system principles and lessons about multilevel stakeholder engagement from our work (Figure on next page). Our inputs (e.g., expertise, partnerships, resources) provide the foundation for the Center’s overarching objectives that create a workflow for our research areas (reflected in Goals #1-4). These objectives are to: (1) evaluate patient, provider, and organizational determinants of variations in care; (2) develop and test innovative care models/health systems interventions to improve care quality and patient experience; and (3) design and test strategies to increase implementation and spread of evidence-based practice to improve effectiveness, impact, and value of VA care. Activities in each research area are then supported by strategic planning, collaboration, dissemination and implementation capacity, education/mentorship, engagement, and evaluation/communication plans) that represent the rest of our strategic plan, in addition to service to VA). Measurable milestones (outputs) and intended impacts (proximal and distal outcomes) will be tracked annually. Associated timelines are in each section of our research areas. Reporting activities for VA and other stakeholders are described.

**Research Focus and Priorities**

The Center’s research focus and priorities are anchored in VA’s Strategic Plan (2018-2024), which will affect operations and clinical care at the VA network (VISN) and VA facility levels. As a result, we will focus on VA foundational services (services the VA will retain in-house), including primary care, women’s health, mental health, and geriatrics. Our focus on high-risk, high-need populations also reflects our broad thematic emphasis on health equity for these groups as prioritized in the Commission on Care report. Our emerging areas reflect additional high-priority topical areas.
For example, complementary and integrative health (CIH) is embedded in the Secretary’s Whole Health Initiative and part of the Comprehensive Addiction and Recovery Act (CARA) as required VA care. Exclusion of specialty care as a foundational service is expected to translate into regional or local “make vs. buy” decisions, which creates demand for research on specialty care access strategies (e.g., regional networks, telehealth), which we will pursue. All of our research areas relate to VA HSR&D research priority areas (e.g., access, women’s health, mental health, long-term care, patient-centered care, health care systems change, implementation science). Our cross-cutting methods reflect needs across our goals and Center objectives, including expertise in patient, provider, and organizational surveys; use of VA and non-VA administrative data; “big data” methods using natural language processing, patient-reported outcomes, and predictive analytics; health informatics; cluster randomized, stepped wedge, and pragmatic trials; multilevel stakeholder engagement; and implementation/quality improvement strategies for spread and scale-up.

Quality Enhancement Research Initiative (QUERI)
HSR&D oversees and facilitates VA’s Quality Enhancement Research Initiative (QUERI), which is designed to improve care by facilitating the adoption of new evidence based treatments, tests, and models of care into routine clinical practice. QUERI is a principal component of VA’s commitment to improving the quality of Veterans’ healthcare.

HSR&D Eligibility:
HSR&D implements the eligibility policy and procedures presented in VHA Handbook 1200.15. Exceptions to the basic requirement that all PIs hold at least a 5/8ths VA appointment are very rare, and in no case, is an exception made without approval of the Chief R&D Officer.

HSR&D Research Career Scientist (RCS):
RCS designation is awarded to established, independent investigators who have distinguished themselves through scientific achievement and contribution to the VA research program via training, mentoring junior VA scientists (clinician and non-clinician), functioning as a resource for the research community, serving on VA research or other local or national committees, directing a core facility, and collaborating with clinician scientists.
HSR&D RCS Award: RCS awards are for established, non-clinician, independent investigators and initially provide up to five years of funding. Career Scientists at the RCS level must have a minimum of six years of independent research support (VA or other), and must have current VA/HSR&D project support.

HSR&D Senior Research Career Scientist (SRCS) Award: Selected individuals who have held a Research Career Scientist award for a minimum of five years may advance to an SRCS award. These senior level awards recognize VA health services researchers who are international leaders in their field. Awards are for seven years and are renewable indefinitely.

**HSR&D Career Development Award:**
The HSR&D is an integral part of VA's research mission to deliver the highest quality of health care to our nation's Veterans. Our investigators seek to discover which treatments and practices not only lead to the best outcomes for Veterans but also represent the most cost-effective and efficient uses of VA resources. For the last twenty years, the HSR&D Research Career Development Program (RCDP) has been our most important investment in human capital to conduct high quality, cutting edge research that complements the efforts of the other services within VA's Office of Research and Development. The goal of the RCDP is to continue to make VA a first-choice for talented post-docs interested in becoming national leaders in health services research within a supportive, Veteran-focused clinical and mentoring environment. The program is not a training program, however. To be competitive, candidates must demonstrate (through their didactic work, research collaborations, and HSR&D relevant manuscripts) that they have the appropriate level of training, commitment, and potential to position themselves to become independent HSR&D investigators.

**VA Nursing Research Initiative (NRI):**
NRI is an intramural funding mechanism designed to develop and retain talented VA nurse researchers in the areas of particular importance to VA. Program goals include developing doctoral nurses' research skills, encouraging nursing research career opportunities, and developing the capacity of independent nurse investigators within VA. The NRI award is a mentored award to support a discrete, specified, circumscribed program of research and personalized career development and mentoring designed to equip the named investigator with the skills needed to develop a competitive independent Merit Award or prepare the nurse investigator to compete for the more time intensive Career Development Award (CDA-2), which requires a minimum 75% research and training time commitment. Topics should be focused on high priority, VA mission-oriented areas of investigation.

**HSR&D Promotions:**
Positions typically eligible for consideration are those whose primary function is scientific investigation in basic or applied research in the biological, medical, health, physical, veterinary medical, computer, social (including economics), or mathematical (including statistics) sciences; engineering; industrial design; and psychology.

Requirements –
(1) A minimum of 5/8ths time commitment to VA, evidenced by a 5/8ths VA-salaried appointment or an approved eligibility waiver (see Handbook 1200.15).
(2) A record of successful past and current VA research support or successful competition as a principal investigator for significant, extra-VA research funding from a national program that utilizes a standard of scientific merit review equivalent to that of VA, or both.
(3) Publications in peer-reviewed scientific and professional journals widely read within the nominee’s field, particularly as the first or senior author.
(4) Invitations to speak or chair sessions at national or international scientific meetings.
(5) Membership on national scientific advisory or merit review committees or editorial boards of scientific or professional journals.
(6) Recognition by peers as a leader in a research field.
(7) Interaction with clinicians, researchers, and managers in support of the patient care and research and development programs.
(8) An active role in the training of young scientists and in formal teaching.
Rehabilitation Research & Development Service (RR&D)

RR&D is dedicated to the well-being of America's Veterans through a full spectrum of research: from approved rehabilitation research projects, through evaluation and technology transfer to final clinical application. RR&D’s mission is to discover new knowledge to advance optimal rehabilitative health care for Veterans with disabilities, and to create innovations that improve the health and rehabilitative care of Veterans and the Nation.

Merit Review Awards are RR&D’s principal mechanism for funding basic, translational and clinical studies of disorders and diseases of importance to the rehabilitation of Veterans. The goal of RR&D is to maximize functional recovery. Areas of emphasis are broad and expansive encompassing basic scientific research that has strong implications for translation into clinical practice, as well as rehabilitation strategies, interventions and techniques, including prosthetic devices, and reintegration of Veterans into all facets of civilian life. The long-term effects on outcomes of many traditional approaches remain unproven, and as rehabilitation moves forward, researchers must examine efficacy to allow its medical practice to be truly evidence based.

LOI All applicants for research support through the Rehabilitation Research and Development (RR&D) Service are required to submit a Letter of Intent (LOI) each review cycle, including resubmissions and revisions. A description of the proposed project in terms of its objectives, rationale, methods, participants, resource requirements, expected outcomes, technology transfer implications and the impact on the health care delivery system for Veterans should be included. Each application submission must be preceded by an LOI. Applicants may submit more than one LOI per review cycle.

RR&D Eligibility: All applicants (i.e., all persons assigned the PI role) for VA Research funds must hold a minimum 5/8 VA salaried position before a research project can be funded. RR&D establishes Eligibility during the Merit Review Letter of Intent (LOI) process.

RR&D Research Career Scientist (RCS):

The RR&D RCS program is a highly selective program designed to sustain and enhance the research careers of established non-clinician scientists who have demonstrated commitment to Department of Veterans Affairs (VA) rehabilitation research. Salary support for non-clinician scientists historically has been available through a variety of mechanisms, including the Merit Review and the RCS programs. The RR&D RCS program is intended to provide recognition and salary support for outstanding non-clinician scientists in VA. Non-clinician scientists who are either principal or co-principal investigators on VA-funded peer-reviewed research programs and salaried by VA RR&D are eligible to apply for the RCS award (see VHA Handbook 1200.15 at http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1411) VA clinicians who have switched from a clinical career track to a research track or non-clinician scientists who have a record of demonstrated commitment to VA rehabilitation research may also be eligible for the RCS program. Non-clinician scientists contribute to VA research programs not only because of their direct contributions to scientific knowledge, but because they serve as mentors for clinician and non-clinician investigators. They furnish an important expertise that complements the research programs of the clinical staff.

Qualifications: The title, RCS, may be awarded to established, independent investigators who have distinguished themselves through scientific achievement, and who contribute to the VA research program through participation in research activities, including: training and mentoring junior VA scientists; functioning as a resource for the research community; serving on VA research or other committees; and collaborating with clinician investigators. A limited number of these prestigious awards are available for RR&D Service. Applicants must be in receipt of VA research funding or other national peer-reviewed research support. Academic appointments should be at the Associate Professor or Professor level.
**RR&D Career Development Award:**

RR&D CDA applicants for research support through RR&D Service are required to submit a Letter of Intent (LOI) each review cycle. The objective is to promote the professional careers of outstanding clinician scientists committed to conducting biomedical research through a mentored research training program. Implicit in all CDA applications is the understanding that the applicants plan to continue their careers within VA. At the conclusion of the award, it is anticipated that the awardee will continue to work as a VA clinician research scientist and apply for independent funding through mechanisms such as VA Merit Review or other national programs.

**RR&D Promotions** - Positions typically eligible for consideration are those whose primary function is scientific investigation in basic or applied research in the biological, medical, health, physical, veterinary medical, computer, social (including economics), or mathematical (including statistics) sciences; engineering; industrial design; and psychology.

Requirements:

1. A minimum of 5/8ths time commitment to VA, evidenced by a 5/8ths VA-salaried appointment or an approved eligibility waiver (see Handbook 1200.15).

2. A record of successful past and current VA research support or successful competition as a principal investigator for significant, extra-VA research funding from a national program that utilizes a standard of scientific merit review equivalent to that of VA, or both.

3. Publications in peer-reviewed scientific and professional journals widely read within the nominee’s field, particularly as the first or senior author.

4. Invitations to speak or chair sessions at national or international scientific meetings.

5. Membership on national scientific advisory or merit review committees or editorial boards of scientific or professional journals.

6. Recognition by peers as a leader in a research field.

7. Interaction with clinicians, researchers, and managers in support of the patient care and research and development programs.

8. An active role in the training of young scientists and in formal teaching.
VA Grantsmanship

Not only does your science matter in writing a grant what also matters is how you present the grant. It sets the stage of how passionate and dedicated you are to your grant. Past merit review critiques have stated in the critique that the grant was written poorly, hard to understand, objectives are not clearly defined in the grant or overly ambitious, misspellings, and poor grammar.

A few tips on writing a VA good grant:

Always refer to the formatting guidelines in the program announcement. You must also keep in mind that an Administrative Assistant is making sure that you are following the guidelines. They are the first step in the grant review process. There is nothing worse than a proposal being rejected due to exceeding page limits, fonts are less than 11pt, and margins less than .5 inch. Do not use Times New Roman, only acceptable fonts are: Arial, Helvetica, Palatino Linotype, or Georgia typeface. Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.

Check spelling and grammar. Spelling and grammar errors are very annoying to reviewers. They start looking for errors than reviewing your grant.

Do not make your grant too dense. They know how brilliant you are by your Biosketch you do not need to prove it.

Your grant must be relevant to Veterans Healthcare and you should be tailoring your grant for Veterans. Please make sure that they get the honor they deserve and capitalize Veteran.

Do not include any information in the header or footer area of PDF attachments.

Key personnel – please make sure that you have the most qualified personnel in your key personnel. If your grant requires a certain specific specialty make sure you have someone on your project that had the skill set that is needed to perform your grant.

Have an update biosketch as well as an updated biosketch for all your key personnel. The biosketch is important because it is specifically for your grant. The personal statement shows expertise and the commitment of yourself and key personnel on your grant.

Stay within the budget amount and year limits. Do not pad your budget. Well justify the budget. Do not use vague language of why supplies and personnel are needed.
Off-Site Research

VA research is an intramural program derived from clinician observation of the health problems and needs of Veterans. The opportunity to explore research based upon these observations in laboratory and other appropriate settings within VA medical centers provides a strong foundation for this program. However, in rare situations, VA medical centers may be unable to provide sufficient or appropriate space and facilities for specific research projects. To accommodate such programs, ORD reviews and evaluates all VA-funded research proposed to be performed at sites outside VA medical centers or outside VA-leased space previously approved by ORD for research use.

Two types of Off-site Waivers


Note: A partial off-site waiver is required if the principal investigator (PI) will perform any part of the proposed research at a location other than the VA or VA-approved/leased space. An off-site waiver is NOT required for the use of off-site core facilities or if the PI will conduct a part of the proposed research in a collaborator’s research space off site.

B. Full Off-site Waiver.

Note: Full off-site waivers are considered only under special circumstances.

VA Funded Research Just-in-Time Process to Release Funds

When a project is selected for possible funding by the VA, it will be entered into the JIT document management website for processing of the documents that must be submitted to ORD Just-in-Time. All submission of documents is handled by Dr. Sharon R. Saivar; the website currently does not allow direct access by investigators. Dr. Saivar will notified PIs that Just-in-Time document submission is needed are advised to prepare the relevant documents for submission to the local oversight committees (for example, R&D, IRB, IACUC, etc.), and to submit additional documents required for funding approval, i.e., PI assurance, budget revisions, other support, offsite waivers, OMB exemption, QUAD Chart, etc.
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Introduction

I believe that understanding the role of Research Service at GLA requires at least a minimal understanding of how we fit in the larger organization. What follows is a brief, top-down summary of the Department of Veterans Affairs, its leadership, and its mission, vision, core values, and goals. It is helpful to understand these values as we make everyday decisions in the completion of our assigned duties, and it also helps us to set our priorities in that process.

The VA is part of the Administrative Branch of the U.S. government and is a Cabinet level department. The Secretary of the VA is retired U.S. Army General, Eric K. Shinseki, who was nominated for this position by President Obama on December 7, 2008 and confirmed by the U.S. Senate on January 20, 2009. At the next level, we fall under Veterans Health Administration. The VHA is under the leadership of the Under Secretary for Health (USH): Michael J. Kussman, MD. Some of our operations (most significantly, the Office of Research Oversight, ORO, under the Deputy Undersecretary for Health for Operations and Management (DUSHOM, William F. Feely. The Office of Research and Development, ORD also falls under the Deputy Undersecretary and is headed by the Chief Research and Development Officer, or CRADO, Joel Kupersmith, MD

VA Mission Statement

To fulfill President Lincoln’s promise – “To care for him who shall have borne the battle, and for his widow, and his orphan” – by serving and honoring the men and women who are America’s Veterans.

VA Vision

To provide Veterans the world-class benefits and services they have earned – and to do so by adhering to the highest standards of compassion, commitment, excellence, professionalism, integrity, accountability, and stewardship.

VA Core Values

Compassion – We will treat all Veterans and their families with the utmost dignity and compassion. We will provide services in a caring manner, with a sympathetic consciousness of others’ distress together with a desire to alleviate it.

Commitment – Veterans have earned our gratitude and respect. Their health care, benefits, and memorial service needs to drive our actions.

Excellence – We strive to exceed the expectations of Veterans and their families. We strive to perform at the highest level of competence and take pride in our accomplishments.

Professionalism – Our success depends on maintaining a highly-skilled, diverse, and compassionate workforce. We foster a culture that values equal opportunity, innovation, and accountability.

Integrity – We recognize the importance of accurate information. We practice open, truthful, and timely communication with Veterans, employees, and external stakeholders. By carefully listening and responding to their concerns, we seek continuous improvement in our programs and services.
**Accountability** — We will perform in a manner at all times that makes us accountable, responsible, and answerable to Veterans and their families, our leaders and other employees as well as external stakeholders.

**Stewardship** — We will ensure responsible stewardship of the human, financial, and natural resources as well as data and information entrusted to us. We will improve performance through the use of innovative technologies, evidence-based medical practices, and sound business principles.

**Strategic and Enabling Goals**

**Goal 1** — Restore the capability of Veterans with disabilities to the greatest extent possible, and improve the quality of their lives and that of their families.

**Goal 2** — Ensure a smooth transition for Veterans from active military service to civilian life.

**Goal 3** — Honor and serve Veterans in life, and memorialize them in death for their sacrifices on behalf of the Nation.

**Goal 4** — Contribute to the public health, emergency management, socioeconomic well-being, and history of the Nation.

**Enabling Goal** — Deliver world-class service to Veterans and their families through effective communication and management of people, technology, business processes, and financial resources.

**From VHA**

**VHA Mission:** The mission of the Veterans Healthcare System is to serve the needs of America’s Veterans by providing primary care, specialized care, and related medical and social support services. *To accomplish this mission, VHA needs to be a comprehensive, integrated healthcare system that provides excellence in health care value, excellence in service as defined by its customers, and excellence in education and research, and needs to be an organization characterized by exceptional accountability and by being an employer of choice.*

**VHA Vision:** Healthcare Value begins with VA. The new Veterans Healthcare System supports innovation, empowerment, productivity, accountability and continuous improvement. Working together, we provide a continuum of high quality health care in a convenient, responsive, caring manner — and at a reasonable cost.

**VHA Organizations:** Here is a list of all of the organizations in VHA

- Office of Academic Affiliations
- Office of Finance
- Office of Health Information
- Office of the Medical Inspector
- Office of Patient Care Services
- Policy and Planning
- Office of Quality and Performance
- Vet Centers (Readjustment Counseling)
- Veterans Integrated Service Networks
- Patient Safety (National Center for Patient Safety)
- Office of Public Health and Environmental Hazards
The **Office of Research Oversight**: The Office of Research Oversight assures the safety and protection of all subjects, human and animal, involved in VHA research activities.

**And of course:**

**Office of Research & Development**: The Office of Research and Development aims to lead the VHA in providing unique health care importance to Veterans through printing research articles, reports and posting accomplishments.

**ORD Research Programs (national)**

<table>
<thead>
<tr>
<th>VA ORD Research Services</th>
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<tbody>
<tr>
<td><strong>BLR&amp;D</strong></td>
</tr>
<tr>
<td>The <strong>Biomedical Laboratory Research &amp; Development Service</strong> 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.</td>
</tr>
<tr>
<td><strong>CSR&amp;D and CSP</strong></td>
</tr>
<tr>
<td>The <strong>Clinical Science Research and Development Service</strong> 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 <strong>Cooperative Studies Program</strong> 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.</td>
</tr>
<tr>
<td><strong>HSR&amp;D</strong></td>
</tr>
<tr>
<td>The <strong>Health Services Research and Development Service</strong> pursues research at the interface of health care systems, patients and health care outcomes. HSR&amp;D underscores all aspects of VA health care; specifically quality, access, patient outcomes and health care costs.</td>
</tr>
<tr>
<td><strong>RR&amp;D</strong></td>
</tr>
<tr>
<td>The <strong>Rehabilitation Research &amp; Development Service</strong> is dedicated to the well-being of America’s Veterans through a full spectrum of research: from approved rehabilitation research projects, through evaluation and technology transfer to final clinical application.</td>
</tr>
</tbody>
</table>

**Finally, our local GLA mission, vision, and values**

**Our Mission**: Honor America’s Veterans by providing exceptional health care that improves their health and well-being.

**Our Vision**: To be a patient-centered integrated health care organization for Veterans providing excellent health care, research, and education; an organization where people choose to work; an active community partner; and a back-up for National emergencies.

**We Value**: trust, respect, excellence, commitment and compassion
Organizational Responsibilities: Office of Research Administration

The ORA has responsibility for all administrative and budgetary operations of the R&D Service. Under the leadership of the Associate Chief of Staff for Research (ACOS/R), ORA is responsible for assuring the continuing high quality of the facility’s R&D program and the planning and development of the broad objectives of the program so that it supports the patient care mission of Department of Veterans Affairs and the GLA. The ORA, is responsible for the oversight of all research-related activities including the Research Safety and Security Program, the Human Research Protection Program, and the Animal Care and Use Program. The ORA promotes effective communication and working relationships between the facility and its affiliates so adherence to the requirements of the affiliation agreements can be met by all involved parties. In addition, the ORA integrates the needs of the affiliation relationship with the research and patient care needs at the facility.

The ORA has two major components to its overall mission:

To provide support for the scientific mission of the Research program.

To ensure proper oversight of programmatic systems, either directly within ORA or indirectly through support of compliance committees.

In order to accomplish this mission, it must be a priority to facilitate the processing of efficient operations and coordination of each of the sections within ORA to interface with other Services and extramural agencies. This must be done, keeping in mind the organizational mission, values, and priorities as stated above.
Section Responsibilities:

Human Subjects Research Section

Section Head: Elizabeth Corey, PhD, IRB Administrator

Primary Responsibilities:

Communication with customer base and intra-ORA business.
Maintain Federal Wide Assurance (FWA)
Maintain AAHRPP Accreditation Standards
Develop and publish relevant Policies, Forms, and SOPs for the Human Subjects Protection Program.
Adverse and Unanticipated Events
Coordinate and Support the Institutional Review Boards
  Meeting prep
  Triage of incoming submissions
  Recording outcomes in RPTS
  Minutes
  Communication of outcomes/summaries to R&D Coordinator
Triage and coordinate Data Use and Security Plan reviews
Initiation of intramural and extramural correspondence relevant to the HRPP.
Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.

Budget Section

Section Head: Malkia Belcher, Supervisory Budget Analyst

Primary Responsibilities:

Maintain RMS Database
Distribute PI Account Statements (quarterly)
Distribute incoming funding to appropriate Accounts
Maintain and Balance all Control Points
Manage Current Year and Prior Year funding to comply with Guidance Documents
Develop and Publish Policies, Forms, and SOPs for the Budget Section
Tracking of investigator expenditures
Tracking of open obligations
Tracking of GPF activities
Purchasing
Accounts payable
Accounts receivable including APD, RIPA, Impact Costs
Initial approval of the IPA process and obligation of the IPA
Request funds/provide financial documents to CO
Request for Budgetary Support Co-op Studies
Research Career Science Award and CDA needs/excesses
Payroll analysis/projection
Monitoring of all accounts and initiation of corrective action for problems
Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.
Investigator Services Section

**Section Head:** Sharon R. Saivar, DPA, Director Investigator Services Center

**Primary Responsibilities**

Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.
Submission of all VA Grant applications
Eligibility
Off-site waivers
Annual project and final reports to ORD
Research Career Scientist appointments
Centralized Promotions for PIs
Maintain Competency (Education) folders
  1. Orientation checklist
  2. Position Description
  3. Performance Evaluation (last)
  4. Competency assessment form
  5. Licensure and Certifications
  6. Mandatory Training
Portfolio Management
Maintain ePROMiSe database
Maintain Research Human studies project files
Triage incoming submissions
Distribute HRPP submissions to IRB per SOP
Forward IACUC/SRS/R&D Submissions to C&CS per SOP
Maintain Investigator Manual
Credentialing database in RPTS
Training and Education files and Database
Backup on entry doors for Research space
Visitor badges
Timekeeping
Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.

Personnel Section

**Section Head:** Jason Binning, Personnel Section Supervisor

**Primary Responsibilities**

Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.
Timely triage and processing of all documents related to VA hire
PDs
Requests to Recruit
ARPA requests
Personnel Action forms
Changes in tour
Changes in appointment
Terminations and Clearance
Timely triage and processing of all documents related to WOC appointments
Timely triage and processing of all IPA contracts
Reporting to Tech Transfer on WOC status
Primary interface with GLA HR
Performance standards and review

Committees and Compliance Section

Scott Krahl, PhD, Deputy ACOS, Report to the ACOS

Primary Responsibilities

Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.
IACUC admin support
R&D admin support
SRS admin support
Triage all incoming submissions for IACUC, SRS, and R&D
Admin review of incoming submissions
Timely processing of incoming submissions for review
Maintain meeting records
Maintain Animal Studies and Basic Laboratory Science project files
Maintain LASIF files
Maintain policy library
Initiate correspondence to extramural agencies with regard to compliance
Communication of approvals by Subcommittees to R&D and R&D to PIs.

Safety/Security

Jerry Dungan, Biosafety Officer, Reports to the ACOS

Primary Responsibilities:

Notifications to Customers and interfaces regarding any issues related to areas of responsibilities.
Support for the IACUC and SRS for matters related to facilities, safety and security.
Work orders
Interface with other services related to areas of responsibility:
  Engineering
  AMMS
  Pharmacy
  Industrial Hygiene
Animal Compliance

Fredricka Martin, Ph.D, Animal Program Field Compliance Officer, Reports to the ACOS

Primary Responsibilities:

Field support for PIs and Research Staff including:
  Preparation of materials for Committee review
Assist PI’s with in the completion of the Animal Component of Research Protocol (ACORP) form.
Reports to ORO and other outside agencies

Veterinary Medical Unit

Section Head: Mary Knezevich, DVM

Primary Responsibilities:

Maintain AAALAC Accreditation
Maintain Compliance with AWA
Support of Research mission through animal husbandry, surgical, and other support.
Training of VMU staff and Study staff.
# GLA Research & Development

## Contact List

<table>
<thead>
<tr>
<th>WLA Main Telephone Number</th>
<th>Sepulveda Main Telephone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>(310) 478-3711</td>
<td>(818) 891-7711</td>
</tr>
</tbody>
</table>

## Research Administrative Office

<table>
<thead>
<tr>
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<th>Email</th>
<th>Phone</th>
<th>Ext.</th>
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</thead>
<tbody>
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<td>114-326B</td>
<td>41303</td>
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<td>114-330</td>
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<tr>
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<td>818-895-9416</td>
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<td>1-C-111</td>
<td>38020</td>
</tr>
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</table>

## R&D Committees and Compliance

<table>
<thead>
<tr>
<th>Name</th>
<th>Title / Position</th>
<th>Email</th>
<th>Phone</th>
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<tbody>
<tr>
<td>Giselle Henry</td>
<td>R&amp;D Coordinator</td>
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<td>WLA - 83038</td>
</tr>
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<td>Animal Program Field Compliance</td>
<td><a href="mailto:Fredricka.Martin@va.gov">Fredricka.Martin@va.gov</a></td>
<td>WLA - 114-226</td>
<td>SEP - 1-C-113</td>
</tr>
<tr>
<td>John Berard, PhD</td>
<td>IACUC Coordinator</td>
<td><a href="mailto:John.Berard@va.gov">John.Berard@va.gov</a></td>
<td>1-C-111</td>
<td>38021</td>
</tr>
<tr>
<td>Vacant</td>
<td>SRS Field Coordinator</td>
<td></td>
<td>1-C-111</td>
<td>38020</td>
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<tr>
<td>Vacant</td>
<td>Program Assistant</td>
<td></td>
<td>1-C-111</td>
<td>38019</td>
</tr>
<tr>
<td>Margaret Roch, AA, BS</td>
<td>SRS Committee Coordinator</td>
<td><a href="mailto:Margaret.Roch@va.gov">Margaret.Roch@va.gov</a></td>
<td>1-C-111</td>
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</tr>
<tr>
<td><strong>Clinical Research Center (CRC)</strong></td>
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<tr>
<td>Kimberly Panizzon</td>
<td>CRC Coordinator</td>
<td><a href="mailto:Kimberly.Panizzon@va.gov">Kimberly.Panizzon@va.gov</a></td>
<td>500-3259</td>
<td>83529 818 755-8252 (cell)</td>
</tr>
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<table>
<thead>
<tr>
<th><strong>Investigator Services Center</strong></th>
<th></th>
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<tbody>
<tr>
<td>Sharon R. Saivar, DPA</td>
<td>Director, ISC</td>
</tr>
<tr>
<td>David Arnett</td>
<td>Offsite Records Manager</td>
</tr>
<tr>
<td>Arthur Velling</td>
<td>ISC Coordinator</td>
</tr>
<tr>
<td>Rogen Silverman</td>
<td>ePROMISe Manager</td>
</tr>
<tr>
<td>Lynn Warech</td>
<td>Program Assistant</td>
</tr>
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<tr>
<th><strong>Human Research Protection Program (HRRP) (IRB)</strong></th>
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<tbody>
<tr>
<td>Liz Corey, PhD</td>
<td>HRPP Administrator, Education Director</td>
</tr>
<tr>
<td>Vacant</td>
<td>DUSP Coordinator</td>
</tr>
<tr>
<td>Rosemary Connelly, RN</td>
<td>IRB Program Analyst</td>
</tr>
<tr>
<td>Juliet Jimenez</td>
<td>IRB-A Coordinator</td>
</tr>
<tr>
<td>Sam Tran</td>
<td>IRB-C Coordinator</td>
</tr>
<tr>
<td>Vacant</td>
<td>IRB-B Coordinator</td>
</tr>
<tr>
<td>Bobby Sarma, PhD</td>
<td>Mentoring Director</td>
</tr>
<tr>
<td>Akiko Iida-Klein, PhD</td>
<td>HRPP Coordinator</td>
</tr>
<tr>
<td>Lee Thomas</td>
<td>IRB Staff Asst.</td>
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<tbody>
<tr>
<td>Malkia Belcher, MBA</td>
<td>Supervisor, Budget Analyst</td>
</tr>
<tr>
<td>Jennifer Freedman, BS</td>
<td>Budget Technician/Travel Asst.</td>
</tr>
<tr>
<td>Name</td>
<td>Position</td>
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</tr>
<tr>
<td>Jonathan Grier</td>
<td>Budget Analyst</td>
</tr>
<tr>
<td>Michael Montgomery, BA</td>
<td>Budget Technician</td>
</tr>
<tr>
<td>Janice Thompson</td>
<td>Budget Technician</td>
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**Personnel Section**

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<tr>
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<tbody>
<tr>
<td>Jason Binning</td>
<td>Supervisor, Personnel Specialist</td>
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</tr>
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</tr>
<tr>
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<td>114-328</td>
<td>42630</td>
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**Veterinary Medical Unit**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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</tr>
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<tbody>
<tr>
<td>Mary Knezevich, MA, DVM, DACLAM</td>
<td>Veterinary Medical</td>
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</tr>
<tr>
<td></td>
<td>Clinical Veterinarian</td>
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<td></td>
<td>WLA - 49255 SEP - 9396</td>
</tr>
<tr>
<td>Vacant</td>
<td>Facilities Manager/Supervisor</td>
<td></td>
<td>113-VMU</td>
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</tr>
<tr>
<td>Thomas Beeson, RLATG, RVT</td>
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<td>7331</td>
</tr>
<tr>
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</tr>
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</table>

**Brentwood Biomedical Research Institute**

<table>
<thead>
<tr>
<th>Name</th>
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</thead>
<tbody>
<tr>
<td>Kenneth Hickman, PhD</td>
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</tr>
<tr>
<td>Name</td>
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</tr>
</tbody>
</table>
# Appendix B

## Additional IRB Information

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VA GREATER LOS ANGELES - HUMAN SUBJECT RESEARCH INVESTIGATOR GUIDANCE

I. OBTAINING IRB APPROVAL – THE REVIEW PROCESS

A. What are the different regulatory classifications that research activities may fall under?

Submitted activities may fall under one of the following four regulatory classifications:

- **Not “Human Research”:** Activities must meet the DHHS or FDA definition of “research” involving “human subjects” for the activity to fall under IRB oversight. Activities that meet neither definition of “Research involving “Human Subjects” are not subject to IRB oversight or review.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the IRB, not the investigator, to determine whether Human Research is exempt from IRB review.

- **Review Using the Expedited Procedure:** Certain categories of non-exempt Human Research may qualify for review using the expedited procedure.

- **Review by the Convened IRB:** Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

B. AT VAGLA - WHEN A STUDY IS DETERMINED TO BE NON-HUMAN RESEARCH, WHAT FORMS AND PAPERWORK ARE REQUIRED AND WHAT IS THE PROCESS?

**Required forms include:**

1) **R&D Form:** Request to Review
2) **Biosafety Form:** Subcommittee for Research Safety (SRS)
3) **Personnel Forms:** Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for all co-investigators and consultants, and
4) **ANY other forms required by LEAD subcommittee (SRS or IACUC)**
5) **Form 00** (and any specific requests from HRPP Administrator/ IRB Coordinator – such as verification from providing physician that data and/or specimens are de-identified to the receiving researcher)

**Additional requirements: Stand Alone Protocol, grant (if applicable)**

**WHAT IS THE PROCESS:**

- Any application deemed to be research, that is not human research, will receive a signed Form 00 (by the HRPP Administrator or Expedited IRB reviewer) with the determination and an email. In complicated cases where there are restrictions
and/or future human research is planned, a memo may be provided, if required by a funding/external institution or other entity.

- The main subcommittee (Subcommittee or the R&D) will be the holder of the file.
- Per VHA requirements, the research must be overseen if the research is VA Research.

**Below is a flow chart illustrating the process from intake to determination and committee oversight (if appropriate):**
C. AT VAGLA - WHEN A STUDY IS DETERMINED TO BE EXEMPT HUMAN SUBJECT RESEARCH, WHAT FORMS ARE REQUIRED AND WHAT IS THE PROCESS?

Required forms include:

1) **R&D Form:** Request to Review
2) **Biosafety Form:** Biosafety – Subcommittee on Research Safety (SRS) Form
3) **Personnel Forms:** Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for each investigator and consultant on the project
4) **ANY other forms required by LEAD subcommittee (SRS or IACUC)**
5) **IRB Form 1- with exempt criteria and justification completed in the Form 1.**

Additional requirements: **Stand Alone Protocol, grant (if applicable)**

**WHAT IS THE PROCESS:** Any application deemed to be EXEMPT will receive a single IRB determination by an IRB Administrator or IRB member. A memo of IRB exemption will be provided to the PI and to R&D and shared with any other subcommittee, who needs to be informed of the IRB determination. The main subcommittee or R&D will be the holder of the file.

An EXEMPT determination is good for the life of a study, unless the study is modified. However, all MODIFICATIONS to IRB EXEMPT projects require re-review by the IRB to determine if the EXEMPT status still holds.

Annually, the investigator must submit a continuation form to R&D and receive continuing review and R&D approval.

D. AT VAGLA - WHEN A STUDY IS DETERMINED TO BE HUMAN SUBJECT (NON-EXEMPT) RESEARCH, WHAT FORMS ARE REQUIRED AND WHAT IS THE PROCESS FOR REVIEW?

Required forms include:

1) **R&D Form:** Request to Review
2) **Biosafety Form:** Biosafety – Subcommittee for Research Safety (SRS) Form
3) **Personnel Forms:** Staffing List + Alt450 VHA Financial Conflict of Interest Form (regarding Conflict of Interest) for investigators and collaborators
4) **IRB Form 1, AND**
5) **Any materials required – consents, HIPAA and any other necessary materials for advertising or scripts (any materials necessary for interacting with subjects)**

Additional requirements: **Stand Alone Protocol, grant (if applicable)**

**WHAT IS THE PROCESS:** All applications are given a pre-IRB meeting review to triage review process – expedited review or review by the fully convened IRB.
**Triage Process:** All expeditable applications are either approved by the Chair or expedited reviewer or forwarded to the fully convened IRB, if the study cannot be expedited. No study can be disapproved by the Chair or expedited reviewer.

The fully convened IRB then reviews the IRB application, protocol and miscellaneous documents and determines whether the study may be approved, require changes to achieve an approval, tabled or disapproved. The PI will receive a memo with the determination and findings of the IRB and instructions regarding any modifications necessary to achieve an approval, if the study is not approved without contingencies or conditions.

**II. IRB DETERMINATIONS - REVIEWED BY THE FULLY CONVENED IRB**

The IRB may approve research, require modifications to the research to secure approval, table research, defer it or disapprove research:

- **Approval:** Made when all criteria for approval are met. See “How does the IRB decide whether to approve Human Research?”
- **Approved Pending (minor contingencies):** Made when all criteria for approval are met, but minor changes are necessary to achieve a final approval. These minor changes are typically simple changes to documents.
- **Modifications Required to Secure Approval (or approved with conditions):** Made when IRB members require specific modifications to the research before approval can be finalized. This determination indicates that IRB approval criteria are met, however, certain conditions or documents are necessary, requiring review by the Chair and/or a primary reviewer is needed to verify that the modifications ensure that the study meets IRB approval criteria.
- **Deferred:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.
- **Deferred/Tabled:** Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- **Disapproval:** Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications the might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.
III. INVESTIGATOR RESPONSIBILITIES AFTER IRB APPROVAL

A. WHAT ARE MY OBLIGATIONS AFTER IRB APPROVAL?

1) Do not start Human Research activities until you have the final IRB approval letter and have met all contingencies and conditions of that approval letter.

2) Do not start Human Research activities until you have the approval of departments or divisions that require approval prior to commencing research that involves their resources.
3) Do not start Human Research activities until you have received the notification of the ACOS for Research. This notification indicates that all necessary approvals from all entities are in place for the study to begin.

4) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

5) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

6) Personally conduct or supervise the Human Research.
   a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB.
   b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
   d) Protect the rights, safety, and welfare of subjects involved in the research.

7) Submit to the IRB:
   a) Proposed modifications as described in this manual. (See “How do I submit a modification?”)
   b) A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”)
   c) A continuing review application when the Human Research is closed. (See “How Do I Close Out a Study?”)

8) Report the any of the information items to the IRB within five business days.

9) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)

10) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

11) See additional requirements of various federal agencies

B. WHAT DO I REPORT AFTER APPROVAL – MORE IS ELUCIDATED IN THE SECTION – VA REQUIREMENTS: Any non-compliance with IRB, deviations, violations from protocol, serious adverse events and ANY information that is required

C. HOW DO I DOCUMENT CONSENT?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates/

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
• Whenever required by the IRB, the subject’s or representative’s signature is to be witnessed by an individual who signs and dates the consent document.
• For subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
• A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

• The subject or representative signs and dates the short form consent document and the summary.
• The individual obtaining consent signs and dates the short form consent document and the summary.
• The witness to the oral presentation signs and dates the short form consent document and the summary.
• Copies of the signed and dated consent document and summary are provided to the subject or representative.

Documentation in the investigator’s files and/or in the medical record are dependent on VHA Handbook 1907.01 and as required by VHA Handbook 1200.05.

D. HOW DO I SUBMIT A MODIFICATION?

Submit a modification request:

• Complete the Form 6 - attach all requested supplements (including updated Form 1, updated consents, protocols, materials, such as scripts, etc.)
• Provide the requested number of copies to the Investigator Services Center (ISC)
• Maintain electronic copies/paper copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received.
• NOTE: A modification, which requires IRB review may be implemented after IRB approval only, unless other entities are necessary as part of the review process. For example – if a new HIPAA is required, the Privacy Officer has to endorse this, prior to use.

E. HOW DO I SUBMIT CONTINUING REVIEW?

Complete the IRB Form 3 – the Continuation Application –

• Sign the form, and provide any necessary attachments with any necessary signatures as well as the requested number of copies (3 copies) to the ISC Office.
• Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications as a separate request for modification using the Modification Form.
If the approval of Human Research **expires**, all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of federal regulations. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB coordinator and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

**F. HOW DO I CLOSE OUT A STUDY?**

Complete the **“IRB Form 7”**, sign the form and include any necessary attachments and provide the requested number of copies (2) to the ISC Office. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

In addition to closing a study, at VA, investigators have additional responsibilities regarding accounting for disclosures and record retention in compliance with the Record Control Schedule.

**G. UNUSUAL SITUATIONS – EMERGENCY USE AND THE IRB**

**WHAT IF I NEED TO USE AN UNAPPROVED DRUG OR DEVICE IN A LIFE-THREATENING SITUATION AND THERE IS NO TIME FOR PRIOR IRB REVIEW?**

Contact the IRB Office – the HRPP Administrator or an IRB Chair. If there is no time to make this contact, see the EMERGENCY USE CHECKLIST/EXPANDED USE ACCESS (EMERGENCY USE SECTION) for the regulatory criteria allowing such a use and make sure these are followed. You will need to submit a report of the use to the IRB within five days of the use and an IRB application for initial review within 30 days.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is “research” as defined by FDA, the individual getting the test article is a “subject” as defined by FDA, and therefore is governed by FDA regulations for IRB review and informed consent. Emergency use of an unapproved device in a life-threatening situation without prior IRB review is not “research” as defined by FDA and the individual getting the test article is not a “subject” as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic.

Individuals getting an unapproved drug or device in a life-threatening situation without prior IRB review cannot be considered a “subject” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS.
IV. INVESTIGATOR REQUIREMENTS - A REVIEW OF OVERSIGHT AGENCY REQUIREMENTS REGARDING DATA COLLECTION, RETENTION AND RE-USE

A. FEDERAL AGENCY REQUIREMENTS PERTAINING TO COLLECTION/RETENTION OF DATA & SUBJECT WITHDRAWAL

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.

2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.

3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.

4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.

B. ADDITIONAL REQUIREMENTS FOR FDA-REGULATED RESEARCH - DRUG AND DEVICE RECORD KEEPING AN INVESTIGATOR RESEARCH OBLIGATIONS

1. When a subject withdraws from a study:
   a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
   b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained.

through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject’s information.

c. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject’s informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.

d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent.

e. An investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

2. For FDA-regulated research involving investigational drugs:

a. Investigators must abide by FDA restrictions on promotion of investigational drugs:  
   i. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
   
ii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

   iii. An investigator must not commercially distribute or test market an investigational new drug.

b. Follow FDA requirements for general responsibilities of investigators  
   i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.

   ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.

   iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.

c. Follow FDA requirements for control of the investigational drug  

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2 http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?f=fr=312.7  
3 http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?f=fr=312.60  
4 http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?f=fr=312.61
i. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.

ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.

d. **Follow FDA requirements for investigator recordkeeping and record retention**

   i. Disposition of drug:
      1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
      2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.

   ii. Case histories.
      1. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
      2. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

   iii. Record retention: An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

e. **Follow FDA requirements for investigator reports**

   i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.

   ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.

   iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

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6 [http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64](http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64)
iv. Financial disclosure reports:
   1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
   2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

f. Follow FDA requirements for assurance of IRB review
   i. An investigator must assure that an IRB that complies with the requirements set forth in 21 CFR §56 will be responsible for the initial and continuing review and approval of the proposed clinical study.
   ii. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

g. Follow FDA requirements for inspection of investigator's records and reports
   i. An investigator must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62.
   ii. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

h. Follow FDA requirements for handling of controlled substances
   i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

3. For FDA-regulated research involving investigational devices:
   a. General responsibilities of investigators.
      i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of
devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 CFR §50.

**b. Specific responsibilities of investigators**11

i. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining IRB and FDA approval.

ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.

iii. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.

iv. Financial disclosure:
   1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.
   2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.

v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:12

i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

ii. Records of receipt, use or disposition of a device that relate to:
   1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
   2. The names of all persons who received, used, or disposed of each device.
   3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

iii. Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the

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individual's hospital charts, and the nurses' notes. Such records must include:

1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
2. Documentation that informed consent was obtained prior to participation in the study.
3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

d. Inspections

i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

iii. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

e. Prepare and submit the following complete, accurate, and timely reports

i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as

possible, but in no event later than 10 working days after the investigator first learns of the effect.

ii. Withdrawal of IRB approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

iv. Deviations from the investigational plan:
   1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.
   2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
   3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB also is required.

v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

viii. Records identifying subjects: An investigator must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

ix. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

f. Prepare and submit the following complete, accurate, and timely reports15

15 http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150
i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

ii. Withdrawal of IRB approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

iv. Deviations from the investigational plan:
   1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.
   2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
   3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB also is required.

v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

C. Additional Requirements for Clinical Trials

1. Investigator's Qualifications and Agreements
   a. The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
   b. The investigator should be thoroughly familiar with the appropriate use of the investigational product, as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
   c. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
   d. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
e. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

2. Adequate Resources
a. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

b. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

c. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

d. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.

3. Medical Care of Trial Subjects
a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

b. During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illnesses of which the investigator becomes aware.

c. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

d. Although a subject is not obliged to give his/her reasons for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reasons, while fully respecting the subject's rights.

4. Communication with IRB
a. Before initiating a trial, the investigator/institution should have written and dated approval opinion from the IRB for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

b. As part of the investigator's/institution's written application to the IRB, the investigator/institution should provide the IRB with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator’s Brochure to the IRB.

c. During the trial the investigator/institution should provide to the IRB all documents subject to review.

5. Compliance with Protocol
a. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was
given approval opinion by the IRB. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

b. The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazards to trial subjects, or when the changes involves only logistical or administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).

c. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

d. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial subjects without prior IRB approval opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendments should be submitted: a) to the IRB for review and approval opinion, b) to the sponsor for agreement and, if required, c) to the regulatory authorities.

6. Investigational Product

a. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.

b. Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution’s duties for investigational product accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

c. The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product received from the sponsor.

d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.

e. The investigator should ensure that the investigational product are used only in accordance with the approved protocol.

f. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

g. Randomization Procedures and Unblinding: The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly
document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

7. Informed Consent of Trial Subjects
   a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principals that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB's written approval opinion of the written informed consent form and any other written information to be provided to subjects.
   b. The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject’s consent. Any revised written informed consent form, and written information should receive the IRB's approval opinion in advance of use. The subject or the subject’s legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to continue participation in the trial. The communication of this information should be documented.
   c. Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.
   d. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
   e. The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval opinion by the IRB.
   f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.
   g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.
   h. Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
   i. If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be
provided to subjects, is read and explained to the subject or the subject’s legally acceptable representative, and after the subject or the subject’s legally acceptable representative has orally consented to the subject’s participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally acceptable representative, and that informed consent was freely given by the subject or the subject’s legally acceptable representative.

j. Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

i. That the trial involves research.

ii. The purpose of the trial.

iii. The trial treatments and the probability for random assignment to each treatment.

iv. The trial procedures to be followed, including all invasive procedures.

v. The subject's responsibilities.

vi. Those aspects of the trial that are experimental.

vii. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

viii. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

ix. The alternative procedures or courses of treatment that may be available to the subject, and their important potential benefits and risks.

x. The compensation and/or treatment available to the subject in the event of trial related injury.

xi. The anticipated prorated payment, if any, to the subject for participating in the trial.

xii. The anticipated expenses, if any, to the subject for participating in the trial.

xiii. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

xiv. That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

xv. That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential.
xvi. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

xvii. The persons to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

xviii. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

xix. The expected duration of the subject's participation in the trial.

xx. The approximate number of subjects involved in the trial.

k. Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject’s participation in the trial, the subject or the subject’s legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

l. When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject’s legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject’s understanding and, if capable, the subject should sign and personally date the written informed consent.

m. Except as described in 4.8.14, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

n. Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled: a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally. b) The foreseeable risks to the subjects are low. c) The negative impact on the subject’s well-being is minimized and low. d) The trial is not prohibited by law. e) The approval opinion of the IRB is expressly sought on the inclusion of such subjects, and the written approval opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

o. In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval opinion by the IRB, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as
possible and consent to continue and other consent as appropriate should be requested.

8. Records and Reports
   a. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.
   b. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
   c. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.
   d. The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The investigator/institution should take measures to prevent accidental or premature destruction of these documents.
   e. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.
   f. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
   g. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

9. Progress Reports
   a. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.
   b. The investigator should promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

10. Safety Reporting
    a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial
subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authorities and the IRB.

b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

c. For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

d. Premature Termination or Suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:

i. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.

ii. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.

iii. If the IRB terminates or suspends its approval opinion of a trial, the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

11. Final Reports by Investigator: Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the trial’s outcome, and the regulatory authorities with any reports required.

V. REQUIREMENTS FOR VETERANS ADMINISTRATION (VA) RESEARCH

A. PHARMACY REQUIREMENTS

- To receive an investigational drug, you must:
  o Provide the Pharmacy Service or Research Investigational Pharmacy information on each subject receiving an investigational drug through the electronic medical record or other locally approved means. Documentation is to include allergies, toxicities, or adverse drug events related to the
investigational drug, or the potential for interaction with other drugs, foods, or dietary supplements, i.e., herbals, nutriceuticals.

- Ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:
  - Documentation of IRB and any other relevant approvals.
  - A copy of VA Form 10-9012, Investigational Drug Information Record, when applicable.
  - A copy of the current approved protocol.
  - A copy of the informed consent form for each participating subject with all appropriate signatures.
  - Documentation of the IRB continuing review approval.
  - Copies of sponsor-related correspondence specific to the drug(s) as appropriate.
  - Copies of all correspondence addressed to the investigator from the FDA (and other involved authorities) specific to the investigational drug(s) as appropriate.
- Inform the Chief of the Pharmacy Service, the research pharmacy when applicable, and the IRB in writing when a study involving investigational drugs has been suspended, terminated, or closed.
- Comply with all dispensing requirements.
- Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested.
- Comply with all VHA pharmacy requirements regarding receiving, dispensing, storing, and record-keeping for investigational drugs.
- Inform the pharmacy service of the IRB’s and Research and Development Committee’s approval.
- Provide the pharmacy with a signed copy of Form 10-1086 to document each subject’s consent to participate in the study.
- Inform the Chief, Pharmacy Service, and the Research and Development Committee when a study involving investigational drugs had been terminated.
- Maintain a record of the research in the subject’s medical chart.
- Maintain signed and dated consent documents for five years after completion of the research.

B. POST APPROVAL – REQUIRED PROMPT REPORTING TO IRB

- Follow this organization’s procedures to ensure reporting in writing to the IRB within 5 business days of becoming aware of:
  - unanticipated problems involving risks to subjects or others,
  - apparent serious or continuing non-compliance,
  - suspension of IRB approval, termination of IRB approval, and local (i.e., occurring in the reporting individual’s own VA facility)
  - unanticipated serious adverse events in writing to the IRB within five business day.
- This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements.)
classification of a serious adverse event as “anticipated” constitutes serious non-compliance.

• It is the policy of the VA Greater Los Angeles Healthcare System (GLA) that:
  
  o In addition to the requirements for continuing review and submitting protocol amendments, the Principal Investigator must submit to the IRB all post approval reports as defined in this SOP.

• The investigator is responsible for reporting events that are unanticipated problems, serious adverse events, and new information, which meet post-approval reporting criteria within specified time frames.

• After reviewing these reports, the IRB must determine the adequacy of the safeguards in place and make appropriate determinations regarding risks, potential benefits, the adequacy of the consent documents, the provision of updated information to subjects, and the safeguards that are in place to protect human subjects, including subject privacy and the confidentiality of data.

• The Principal Investigator must make any changes to the protocol or recruitment or consent documents as required by the IRB.

• The Principal Investigator is responsible for submitting to the IRB ongoing reports of events that are unanticipated problems, and information regarding the conduct of the approved research. The expertise of the investigator is relied upon to make an initial assessment and determine the relationship of the event to the research activity and to determine if the event warrants a change to the protocol to minimize risks to human subjects and/or a change to the informed consent form to better inform subjects of the potential risks and the procedures needed to minimize such risks.

• Not all adverse events, violations, incidents or deviations are unanticipated problems. Examples are provided below of the types of events that do constitute unanticipated problems and, therefore, must be reported. There are also examples of events that need to be reported whether or not they are unanticipated problems.
The Office of Research Oversight provides the following flow chart, which is instructive regarding required reports of SAEs, and serious problems and the IRB review:

- A VA employee becomes aware of a LOCAL DEATH, a LOCAL SAE, or a SERIOUS PROBLEM in VA research that appears to be BOTH UNANTICIPATED (i.e., new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population) and RELATED to the research (i.e., reasonably regarded as caused by, or probably caused by, the research).
- The investigator must ensure IMMEDIATE ORAL NOTIFICATION of the IRB and WRITTEN NOTIFICATION WITHIN 5 BUSINESS DAYS.
- The IRB MUST ALERT ORO (by e-mail or telephone) within 2 BUSINESS DAYS after receiving oral notification.
- The Facility Director and ACOS/R&D must receive notification concurrent with ORO.
- **WITHIN 5 BUSINESS DAYS** after receiving written notification, the IRB chair or a qualified IRB member-reviewer must DETERMINE and DOCUMENT whether any actions are warranted to eliminate apparent IMMEDIATE HAZARDS to subjects.
- The IRB MUST REVIEW the incident and the determination of the IRB chair or qualified IRB member-reviewer at its next CONVENED MEETING and must DETERMINE and DOCUMENT that:
  - The incident was SERIOUS AND UNANTICIPATED AND RELATED to the research; or
  - There was INSUFFICIENT INFORMATION to determine whether the incident was serious and unanticipated and related; or
  - The incident was NOT SERIOUS and/or the incident was NOT UNANTICIPATED and/or the incident was NOT RELATED.
- The convened IRB must also DETERMINE and DOCUMENT:
  - Whether any PROTOCOL OR INFORMED CONSENT MODIFICATIONS were warranted, and if so,
  - Whether investigators must NOTIFY or SOLICIT RENEWED/REVISED CONSENT from previously enrolled subjects, and if so, when and how consent is to be DOCUMENTED.
- For DEATHS, the IRB must notify the FACILITY DIRECTOR and ACOS/R&D OF ALL DETERMINATIONS WITHIN 5 BUSINESS DAYS.
- For SAEs or PROBLEMS, the IRB must notify the FACILITY DIRECTOR and ACOS/R&D WITHIN BUSINESS DAYS after its meeting if:
  - Actions were taken to ELIMINATE HAZARDS to subjects; or
  - The incident was SERIOUS AND UNANTICIPATED AND RELATED TO THE RESEARCH or there was INSUFFICIENT INFORMATION to make the determination, or
  - PROTOCOL OR INFORMED CONSENT MODIFICATIONS were warranted.
- The FACILITY DIRECTOR must REPORT the incident to ORO WITHIN 5 BUSINESS DAYS after notification.

* Additional reporting may be required under local SOPs or by external agencies (such as FDA or OHRP) or sponsors. If in doubt, check with the relevant entities.
Below is an instructive flow chart regarding non-compliance reporting:

**C. ROUTINE REQUIREMENTS OF VA INVESTIGATORS**

- The principal investigator, local site investigator, and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the local VA facility’s SOPs, regarding the conduct of research and the protection of human subjects.
The responsibilities of the investigator may be defined in the protocol or IRB application. Specifically, the principal investigator’s and local site investigator’s responsibilities include, but are not limited to

- **Disclosing Conflicts of Interests.** This means disclosing to the IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.

- **Ensuring Adequate Resources.** This means ensuring there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

- **Ensuring Qualified Research Staff.** This means ensuring research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study. In a protocol, study team members are generally identified by name or by title.

**D. PERSONNEL IN VA RESEARCH – CHANGES DURING A STUDY OVERSIGHT – APPOINTMENTS**

- If a study team member is identified **by name** in the IRB-approved protocol, a replacement or termination of their role constitutes a change in the protocol. Such a change requires IRB approval (e.g., if an IRB-approved protocol specifically identified the name of a medical monitor and later another individual was identified to replace the medical monitor, the protocol would require an amendment reflecting the change in the name of the medical monitor. This protocol change would require IRB approval prior to initiation of the change, unless it was necessary to eliminate apparent immediate hazards to the subjects).

- If a study team member is replaced by another individual and the IRB-approved protocol identifies the person by title and not name, a replacement by another individual with the same title is not a protocol change.

- **No IRB approval is required** (e.g., if a principal investigator appointed a new research study coordinator to replace the original research study coordinator in an IRB-approved protocol when neither is mentioned by name, the replacement in personnel does not require approval by IRB because the protocol remains unchanged).

- IRB may also require a specific individual(s) by name to be part of the study team as a condition for IRB approval of the research. In that case, a proposed change in that specific individual would require IRB approval.

- **NOTE- PI changes must be prompt:** Promptly Reporting Changes in principal investigator or local site investigator. This means promptly reporting any changes in the principal investigator or local site investigator to the IRB. Changes in other key research staff, if any, must be reported at
time of continuing review, or sooner as required by local SOPs. These changes include, but are not limited to, additions to or loss of staff. Changes in the principal investigator, local site investigator, Co-principal investigator, or Co-local site investigator of an IRB-approved project must be evaluated and approved by IRB to ensure the new individual meets the criteria described in 38 CFR §16.111.

E. LAST DETAILS - STARTING A STUDY AT VA GREATER LOS ANGELES – ENSURING COMPLIANCE TO PROTOCOL & VA REQUIREMENTS

- **Ensuring Complete Information in Research Protocol.** This means ensuring the research protocol contains all required information.
- **Obtaining Written Approvals.** This means obtaining written approval(s) before initiating research. Before initiating the research study at a given site, IRB approval must be obtained in writing from the Chair or other voting member of the IRB, and all other committees (e.g., R&D Committee), subcommittees, and other approvals according to applicable local, VA, and other Federal requirements.
  - *For a VA multi-site study,* not only the principal investigator, but also all local site investigators, must obtain such approvals from the relevant local VA facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other Federal requirements.
  - *Research cannot be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local ACOS for R&D.*
- **Implementing the Study as Approved.** This means ensuring the study is implemented as approved by the IRB and in accordance with other required approvals and with all applicable local, VA, and other Federal requirements including, when applicable, those for research involving investigational drugs or investigational devices.
- **Maintaining Investigator’s Research Records.** This means maintaining written documentation on file that the protocol is being implemented as approved by IRB and in accordance with other required approvals.
  - Retain research records until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).
  - Research records include the following when relevant to the study:
    - Copies of all IRB-approved versions of the protocol and amendments.
    - Case report forms and supporting data, including, but not limited to, signed and dated informed consent forms and HIPAA authorizations.
    - Documentation on each subject including, but not limited to:
      - Informed consent,
      - Interactions with subjects by telephone or in person,
      - Observations,
      - Interventions, and
• Other data relevant to the research study, including, but not limited to:
  o Progress notes,
  o Research study forms,
  o Surveys, and
  o Questionnaires.
• Reports of adverse events.
• Data analyses.
• Reports including, but not limited to, abstracts and other publications.
• All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities including, but not limited to, IRB, R&D Committee, ORO, and FDA.
  o Documents must be maintained so that they may be audited by the facility RCO or other entities according to applicable sponsor, local, VA and other Federal requirements, and
  o An Accounting of Disclosure must be maintained for each and every disclosure of information from this study to a non-VA entity. NOTE: The facility Privacy Officer can assist in providing a mechanism to account for this disclosure.

F. INFORMED CONSENT – PROCESS, DISCLOSURE OF INFORMATION AND DOCUMENTATION

The process

o Obtaining Informed Consent. This means ensuring that no human being is involved as a subject in research covered by this Handbook unless legally effective informed consent of the subject or the subject's legally authorized representative has been obtained (38 CFR §16.116). The informed consent must be obtained and documented prospectively (i.e., no screening or other interaction or intervention involving a human subject can occur until after the IRB-approved informed consent requirements have been met). The only exceptions are if the IRB of record determines the research is exempt, or approves a waiver of informed consent, or approves a waiver of the signed informed consent form.

o Designating Responsibility for Obtaining Informed Consent. If the principal investigator or local site investigator does not personally obtain informed consent, the investigator must formally and prospectively designate to another research team member in writing the protocol or the application for IRB approval the responsibility for obtaining informed consent, whether or not a waiver of documentation of informed consent has been approved by the IRB. This designee must be a member of the research team.

• Any person designated to obtain informed consent must receive appropriate training and be knowledgeable enough about the protocol to answer the questions of prospective subjects.
The principal investigator or local site investigator does not have to
designate the individual by name, but can designate the position(s) title in
the protocol or the application for IRB approval.

- **Version of Informed Consent Form.** The most current IRB-approved version
  of the Research Consent Form, for each study (or the most current IRB-
  approved electronic version of the consent must be used as the informed
  consent form.

- **Circumstances Under Which Informed Consent is Obtained.** The
  investigator, or designee, must seek informed consent only under
  circumstances that:
  - Provide the prospective subject or legally authorized representative
    sufficient opportunity to consider whether or not to participate, and
  - Minimize the possibility of coercion or undue influence.

- **Usual Care.** The investigator, or designee, must ensure the Informed Consent
  process clearly defines for the subject which potential risks are related to the
  research and, therefore, must be discussed with the research team, versus
  those associated solely with usual care provided by the subject’s health care
  provider. The informed consent process must include language advising
  subjects to review the risks of the latter with their health care providers.

---

**Documentation of Informed Consent – the Document**

i. When documentation of informed consent is not waived by IRB, the
investigator or designee must ensure the documentation of consent occurs
as follows:

1. The signature and date of the subject or the subject’s legally
   authorized representative, and
2. The signature and date of the person obtaining the informed consent,
   and
3. The signature of the witness and the date of the subject’s or legally
   authorized representative’s signature was witnessed, if required by
   IRB. (e.g., the IRB may require a witness if the study involves an
   invasive intervention or an investigational drug or device.) A witness
   is always required when a short form consent is employed.

ii. The witness is required to witness only the subject’s or subject’s
    LAR’s signature, not the informed consent process (e.g., if the subject
    does not want the witness to know the nature of the research study),
    unless the sponsor or IRB requires the witness to witness the informed
    consent process.

iii. The witness cannot be the person who obtained informed consent from
    the subject, but may be another member of the study team or may be a
    family member.
iv. If use of facsimile is approved by IRB, the subject may submit the signed and dated informed consent form to the investigator or designee by facsimile.

- **Storage of Signed Informed Consent Forms.** The investigator must ensure all original signed and dated forms are in the investigator’s research files, readily retrievable, and secure.

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**Consistency between documents – Consent & HIPAA**

*Ensuring Consistency of Informed Consent Form, Protocol, and HIPAA Authorization.* This means ensuring the language in the informed consent form is consistent with that in the protocol and, when applicable, in the HIPAA authorization.

*Ensuring HIPAA Authorization is Obtained.* This means ensuring that no human being is involved as a subject in research unless the investigator or a designee formally and prospectively designated in writing in the protocol by the investigator has obtained legally effective HIPAA authorization for the use and disclosure of the subject’s PHI, or has obtained Privacy Board or IRB-approved waiver of HIPAA authorization.

If the investigator requires a waiver or alteration of the HIPAA authorization, the investigator must provide the Privacy Board or IRB with information sufficient for the Privacy Board or IRB to find that such waiver or alteration is necessary.

Investigators can obtain and *use real Social Security numbers only when real Social Security numbers are required to meet the specific aims of the research protocol or to enter information into the subjects’ health records.* The collection and use of real Social Security numbers must be approved by IRB, and the investigators must follow all applicable VA and other Federal requirements for obtaining and using real Social Security numbers.

---

**Other Contact with subjects**

- *Ensuring Appropriate Telephone Contact with Subjects.* This pertains to contacting the subject by telephone. Research team members are prohibited from requesting Social Security numbers by telephone.

- Initial Contact. During the recruitment process, ensuring the research team makes initial contact with the potential subject in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research (e.g., if the potential subject has diabetes, the subject may indicate a desire to be notified of any diabetes-related research studies). The initial contact must provide a telephone
number or other means that the potential subject can use to verify the study constitutes VA research. NOTE: One source of information about clinical trials that can be shared with potential subjects is the NIH clinical trials Web site (http://www.clinicaltrials.gov) where VA clinical trials are listed.

- **Later Contact.** Ensuring the research team begins telephone calls to the subject by referring to previous contacts and, when applicable, the information provided in the informed consent form, and ensuring that the scope of telephone contacts with the subject is limited to topics outlined in IRB-approved protocols and informed consent forms.

**Consent for audio/video-research Involving Collection Of Data From Voice, Video, Or Photographs Made For Research Purposes**

- Informed consent for research must be obtained from each research subject before taking photographs or making voice or video recordings that will be used for research purposes.
- VA Form 10-3203 documents permission for pictures, video, and voice recordings to be made or taken or this may be documented in the informed consent itself.
- If the IRB waives documentation of consent, the recording must include the subject(s) (in the case of a focus group) agree to be recorded.
- When information is recorded data that is shared may not be shared outside the VA unless a HIPAA Authorization must be signed.

G. **MISCELLANEOUS RECORD KEEPING REQUIREMENTS (E.G. TRANSFERRING STUDIES, CLOSE OUT PAPERWORK RESPONSIBILITIES, LAB REQUIREMENTS…)**

- **Transferring of Records.** This means transferring of records by VA upon departure of the investigator. If the investigator leaves VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility’s research office. The approval must be obtained from the first VA facility’s research office, any other relevant individuals or offices according to VA and local requirements (e.g., compliance, privacy, or Information Security Officers and the sponsor.) The investigator is not the grantee, nor does the investigator own the data.
- **Ensuring Appropriate Research Laboratory Test Reporting.** This means ensuring research laboratories not report laboratory results that are used...
for diagnosis, treatment, and prevention of disease in patients, unless the research laboratories are properly accredited and meet all requirements of 42 CFR §493.

- **Providing for Privacy and Confidentiality.** This means the investigator provides for privacy and confidentiality. To facilitate review of the protocol by the Privacy Officer, the investigator must either dedicate specific sections of the protocol to privacy and confidentiality, or the investigator must develop an additional document that specifically addresses all privacy and confidentiality issues in the protocol; this becomes part of the IRB protocol file. The description needs to be sufficiently specific for the reader to understand how this requirement protects the subject’s privacy and the confidentiality of the data. These procedures must be in compliance with all applicable VA and other Federal requirements.

- **Providing for Information Security.** This means the investigator provides for an information security plan. To facilitate review of the protocol by the Information Security Officer, the investigator must either dedicate specific sections of the protocol to information security, or the investigator must develop an additional document that specifically addresses all information security issues in the protocol; it becomes part of the IRB protocol file. The plan must clearly identify and include, but not be limited to:
  
i. Whether or not individually identifiable information is to be collected or used;
  
ii. How the data is to be collected or acquired;
  
iii. Where the data (original and all copies) is to be stored and corresponding security systems;
  
iv. How the data is to be transported or transmitted from one location to another;
  
v. Who is to have access to the data and how they are to access it (anyone who has access to the data is responsible for its security);
  
vi. All entities or individuals outside VHA to whom the data is to be disclosed, and the justification for such disclosure and the authority (e.g., the HIPAA authorization);
  
vii. Who is to have access and be responsible for the security of the information (e.g., the Coordinating Center, the statistician, and principal investigator who has ultimate responsibility);
  
viii. Mechanisms used to account for the information;
  
ix. Security measures that must be in place to protect individually identifiable information if collected or used; and
  
x. How and to whom a suspected or confirmed loss of VA information is to be reported.

- **Providing for Reuse of Data.** This means the investigator, if the data may be reused in other studies, describes the research data repository in which the data is to be stored. There must be a research informed consent and a HIPAA authorization associated with the protocol unless these requirements are waived by the IRB. If the IRB does not waive the
requirements then the informed consent and HIPAA authorization content must include language on the uses and disclosures of the data as defined in the protocol as well as information on how privacy and confidentiality will be maintained and how the data will be secured. If the creation and operation of the data repository is not included in the data collection protocol, there must be a separate IRB-approved protocol for the creation and operation of the data repository.

H. SPECIAL SUBJECT POPULATIONS - VA (AND DHHS) REQUIREMENTS

Vulnerable Subjects

- Whenever VA has more stringent requirements than DHHS for protection of vulnerable individuals or vulnerable populations as research subjects, all VA requirements must be met.
- Where relevant, the IRB needs to document why it considers an individual or population to be vulnerable, and that adequate safeguards have been included in the study to protect the rights and welfare of subjects who are likely to be vulnerable.
- Individuals or populations that may be temporarily or permanently vulnerable include, but are not limited to, those who:
  i. Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged).
  ii. Lack comprehension of the research and its potential risks (e.g., educationally disadvantaged, dementia, schizophrenia, depression).
  iii. Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault).
  iv. Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).
- The following populations are considered categorically vulnerable and have specific VA requirements for their inclusion in research:
  i. Fetuses. Research in which the focus is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue), must not be conducted by VA investigators while on official duty, or at VA facilities, or at VA approved off-site facilities.
  ii. Neonates. Research related to neonates including, but not limited to, observational or interventional research, must not be conducted by VA investigators while on official duty, or at VA facilities, or at VA approved off-site facilities.
  iii. Pregnant Women
  iv. Prisoners
  v. Children
  vi. Subjects who Lack Decision-making Capacity.
If a subject becomes incarcerated during the course of a study:

- Investigators must notify the IRB as soon as they become aware that the subject has been incarcerated.
- The investigator must make a determination as to whether or not it is the best interests of the subject to remain in the study, or if the subject can be safely withdrawn from the study.
- If the investigator determines it is in the best interest of the subject to remain in the study, the subject’s continued participation in the study is contingent on the IRB’s reviewing and approving such participation. The IRB approval must comply with 45 CFR §46.301-306.
- After IRB and other relevant approvals (e.g., from the penal system) for the incarcerated subject’s continued participation in the study have been obtained, a waiver must also be obtained from the Chief Research and Development Officer.
- The investigator must comply with all applicable requirements including, but not limited to, applicable court, penal system, and local, VA, and other Federal requirements.

Research Involving Children

- Research involving children cannot be conducted by VA investigators while on official VA duty, using VA resources, completely or partially in a VA facility or at a VA-approved off-site facility unless a waiver has been granted by the Director of the Facility, which is based on the recommendations by the IRB and R&D Committee. VA regards research involving biological specimens or data obtained from children is considered to be research involving children.
- Prior to requesting a waiver, the following criteria must be met:
  i. The study represents no greater than Minimal Risk as determined by the IRB.
  ii. The study meets all requirements in 45 CFR §46, Subpart D, Additional Protections for Children Involved as Subjects in Research, Sections 46.401 through 46.404, and 46.408.
  iii. The IRB reviewing the study has appropriate membership to represent children’s interests and pediatric expertise.
  iv. The IRB reviewing the study has specific SOPs regarding children in research.
  v. The VA facility Director certifies that the facility is able to respond to pediatric emergencies if the study includes interactions with children at the VA facility.
  vi. If the sponsor of the research is not VA, the facility Director makes certain that the sponsor of the research has procured appropriate liability insurance.
**Research Involving Persons Who Lack Decision-Making Capacity**

- Persons who lack decision-making capacity are not to be subjects in research simply because they are readily available.
- No individual who lacks decision-making capacity may participate in VA Research until the IRB has reviewed and approved that individual’s, or that class of individuals’, participation in a given study.
- An individual is presumed to have decision-making capacity unless any one or more of the following apply:
  1. It has been documented by a qualified practitioner in the individual’s medical record in a signed and dated progress note that the individual lacks capacity to make the decision to participate in the proposed study. NOTE: The qualified practitioner may be a member of the research team.
  2. The individual has been ruled incompetent by a court of law.
  3. The investigator has consulted with a qualified practitioner (who may be a member of the research team) about the individual’s decision-making capacity before proceeding with the informed consent process.
- Individuals, who because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity must be evaluated by a qualified practitioner (who may be a member of the research team), to determine the individual’s ability to provide informed consent. This evaluation must be performed as described in the IRB-approved protocol. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative must provide informed consent. If the subject regains decision-making capacity, the investigator or designee must repeat the informed consent process with the subject, and obtain the subject’s permission to continue with the study.

I. **SPECIAL CATEGORIES OF RESEARCH: INTERNATIONAL RESEARCH, PREPARATORY TO RESEARCH AND WHEN OTHER AGENCIES (NOT FDA ARE SPONSORS OR COLLABORATORS) REQUIRING SPECIAL APPROVALS**

**International Research:**

- Research conducted at U.S. military bases, ships, or embassies is not considered international research.
- All individuals who participate as subjects in research at international sites must be provided appropriate protections that are in accord with those given to research subjects within the U.S., as well as protections considered appropriate by local authority and custom at the international site (38 CFR §16.101(g)).
• VA international research is defined as any VA-approved research conducted at international sites (not within the U.S., its territories, or Commonwealths); any VA-approved research using either human biological specimens (identified, de-identified, or coded) or human data (identified, de-identified, or coded) originating from international sites; or any VA-approved research that entails sending such specimens or data out of the U.S.
  i. This includes sending such specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site). It also includes a VA’s serving as a coordinating center for an international research project.
  ii. Multi-site trials are covered under this definition if any of the following apply:
    1. VA is a sponsor;
    2. VA functions as the coordinating center;
    3. VA subcontracts to a foreign site;
    4. The investigator for the total study is a VA investigator; or
    5. The VA investigator is specifically collaborating with an international investigator and the VA investigator sends data or human biological specimens outside the U.S., or receives them from outside the U.S.
    6. NOTE: This requirement does not apply if VA is only one of the participating sites and the trial does not meet the preceding conditions.

• Any international research REQUIRES medical center director approval, based on the recommendations of the IRB, R&D, which must also meet certain criteria
  i. All international sites must hold an international FWA, and the research must be approved by the IRB or Research Ethics Board of the participating site(s) that are listed on the international FWA.
  ii. When conducting international research, the investigator is responsible for:
    1. Obtaining approval from the facility Director.
    2. Meeting all criteria necessary for the waiver

  Preparatory To Research: Data repositories (including VA medical records) may be used (i.e., accessed) by VA investigators for activities that are preparatory to VA research without the requirement to obtain either a HIPAA authorization from the subject or waiver of HIPAA authorization by an IRB or Privacy Board. This includes use of PHI for the preparation of a research protocol prior to submission to the IRB(s).

• “Preparatory to research” activity is the only instance of access for research purposes allowed in VHA without a written HIPAA authorization signed by the individual, a waiver of HIPAA authorization by an IRB or Privacy Board, or approval by the IRB(s). This access is granted only to VHA researchers.
• Non-VHA researchers may not access VHA data for reviews preparatory to research. Additionally, the following holds true:
  • The investigator must make the representations necessary for preparatory access as required by the HIPAA Privacy Rule and document it in the investigator's research files. The representations required by the HIPAA Privacy Rule are:
    i. (1) The access to PHI is only to prepare a protocol;
    ii. (2) No PHI will be removed from the covered entity (i.e., VHA); and
    iii. (3) The PHI accessed is necessary for preparation of the research proposed.
  • Only aggregate data may be recorded in the researcher’s files, and these aggregate data may be used only for background information, to justify the research, or to show that there are adequate numbers of potential subjects to allow the investigator to meet enrollment targets or sample size requirements.
  • Individually identifiable health information may not be recorded.
  • Data or information reviewed may not be used for contacting or recruiting subjects.
  • Investigators must comply with all other access requirements set by the repository of interest.
  • Requirements for Data Use Agreements (DUA) or Data Transfer Agreements (DTA) must be met.
  • Pilot studies are full-fledged research studies that must be approved by the IRB(s), when human subjects are involved. Pilot studies are not considered to be “activities preparatory to research.”
  • No formal IRB determination of exemption from human subject protection requirements is needed if all of the conditions listed in paragraph 57 are satisfied.

**Participation Of Non-Veterans As Research Subjects:** VA research needs to be relevant to Veterans or active duty military personnel. The investigator must justify including non-Veterans in a VA research protocol, and the IRB must review the justification for inclusion of non-Veterans and specifically approve entering non-Veterans into the study before any non-Veterans can be recruited. The IRB must appropriately document in the IRB minutes or IRB protocol file its determinations regarding participation of non-Veterans in the study.

  • Outpatient Care for Research Purposes. Any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (38 CFR §17.92).
  • Hospital Care for Research Purposes. Any person who is a bona fide volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (38 CFR §17.45).
• Other Research. Non-Veterans may be entered into an approved VA research study when the investigator can present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans’ family members), and the research is relevant to the care of Veterans or active duty military personnel.
• VA regulations require the VA to provide care for all research-related injuries including those studies that are considered Minimal Risk.
• VA regulations pertaining to research involving human subjects do not permit data obtained from patients to be classified as human subject research (as those terms are defined by VA regulations), nor may the outcome of such care be included in any report of a research activity subject to VA regulations pertaining to research involving human subjects (as those terms are defined by VA regulations).

Student and Other Trainee Research at Veterans Administration (VA) Facilities
• Only students and other trainees (including residents and fellows), including VA employees, from schools with an academic affiliation agreement consistent with current VHA policy, may serve as investigators within this VA facility, or use data, or human biological specimens that have been collected within VA for clinical, administrative, or research purposes. A waiver may be obtained from the CRADO under special circumstances.
• A VA investigator sufficiently experienced in the area of the trainee’s research interest must serve as investigator or co-investigator and is responsible for oversight of the research and the trainee. The investigator or co-investigator is responsible for ensuring the trainee complies with all applicable local, VA and other Federal requirements.
• In conducting the research, the trainee must comply with all VA and other Federal and local institutional requirements, including those related to research, information security, and privacy.
• If the trainee does not complete all aspects of the research prior to leaving VA, the VA employee serving as the investigator or co-investigator must ensure the protocol is completed or terminated in an orderly fashion, and in accordance with all applicable local, VA, and other Federal requirements.

J. ADDITIONAL REQUIREMENTS WHEN RESEARCH IS FUNDED BY OTHER AGENCIES

Department of Defense (DOD) Research
1. When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.

3. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.

4. There may be specific educational requirements or certification required.

5. Other specific requirements of the Department of Defense (DOD) research be found in the IRB SOP for VAGLA.

Department of Energy (DOE) Research

1. You must report the following within ten business days to the Department of Energy human subject research program manager
   a. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
   b. Any suspension or termination of IRB approval of research.
   c. Any significant non-compliance with HRPP procedures or other requirements.

2. You must report the following within three business days to the Department of Energy human subject research program manager-Any compromise of personally identifiable information must be reported immediately.
Appendix C

Information and Templates

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**DEPARTMENT OF VETERANS AFFAIRS**
**RESEARCH AND DEVELOPMENT INFORMATION SYSTEM**
**INVESTIGATOR DATA**

1. **NAME:** Leonard Hofstadter
2. **DEGREE:** MD
3. **SSN:**

4. **CID:** LHOFSTADTER
5. **TELEPHONE:** 310-268-5555

6. **MAIL CODE:** 151
7. **E-Mail:** leonard.hofstadter@va.gov

8. **VA TITLE:** Staff Physician

9. **UNIVERSITY APPOINTMENT:**
   - **a. Academic Rank**
     - **Code:** 05
     - **Professor**
     - **(Enter name of Academic Rank; if code = 00, skip to Item 5)**
   - **b. University Administrative Title**
     - **Code:** 00
     - **Radiology**
     - **(If code = 99, enter name of University Administrative Title)**
   - **c. University Department**
     - **Enter name**
   - **d. Department Section/Division**
     - **Enter name**
   - e. **University Name**
     - **UCLA**
     - **(Enter name of University)**

10. **DIPLOMATE STATUS, BOARD CERTIFIED:**
   - **Yes**
   - **4 No**
   - **NOT APPLICABLE**

11. **SPECIALTY:**
    - **Code:** 33
    - **Nuclear Medicine**
    - **(If code = 99, enter name of Specialty)**

12. **SUBSPECIALTY:**
    - **Code:**
    - **(If code = 99, enter name of Subspecialty)**

13. **VA EMPLOYMENT**
    - **Code:** 4
    - **FULL-TIME**

14. **VA SALARY SOURCE:**
    - **Code:** 4
    - **VA FUNDS OTHER THAN R&D**
    - **MEDICAL RESEARCH (PROGRAM 821) FUNDS**
    - **HSR&D (PROGRAM 824) FUNDS**
    - **REHAB R&D (PROGRAM 822) FUNDS**
    - **COOPERATIVE STUDIES (PROGRAM 825) FUNDS**
    - **NOT SALARIED BY VA**

15. **VA HOSPITAL SERVICE:**
    - **Code:** 16
    - **Nuclear Medicine**
    - **(If code = 99, enter name of VA Hospital Service)**

16. **VA HOSPITAL SECTION:**
    - **(If applicable, enter name of Hospital Section)**

17. **PRIMARY RESEARCH INTEREST:**
    - **Code:** 21
    - **Nuclear Medicine and Radiation**
    - **(If code = 99, enter name of Primary Research Interest)**

18. **SECONDARY RESEARCH INTEREST:**
    - **Code:** 39
    - **Bioengineering**
    - **(If code = 99, enter name of Secondary Research Interest)**

**INVESTIGATOR’S SIGNATURE ________________________ DATE ________________**

VA FORM 10-5368
Jan 1997

PART I - PAGE 18
5a. **ACADEMIC RANK:** The default Academic Rank for each Series is shown. If actual rank is different, or code is 06, enter name.

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<thead>
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<th>Code</th>
<th>Rank Description</th>
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<td>Instructor Series</td>
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5b. **UNIVERSITY ADMINISTRATIVE TITLE:** The default University Administrative Title for each Series is shown. If actual title is different, or code is 99, enter name.

<table>
<thead>
<tr>
<th>Code</th>
<th>Title Description</th>
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<tbody>
<tr>
<td>01</td>
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<tr>
<td>02</td>
<td>Division Chief Series</td>
</tr>
<tr>
<td>03</td>
<td>Dean Series</td>
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<tr>
<td>04</td>
<td>Associate Professor Series</td>
</tr>
<tr>
<td>05</td>
<td>Professor Series</td>
</tr>
<tr>
<td>06</td>
<td>Resident/Fellow/Trainee/Other</td>
</tr>
</tbody>
</table>

6. **DIPLOMATE STATUS, BOARD CERTIFIED:** Physicians, Dentists, Psychologists - Check YES or NO. Non-physicians - Check NOT APPLICABLE.

7. **SPECIALTY:** Select Board or area of training or expertise. If 99 is selected, enter name in space provided.

8. **SUBSPECIALTY:** Physicians - Enter code for ONE Board or area of training, or 00 (not applicable). If 99 is selected, enter name. Non-physicians - enter 00.

9. **HOSPITAL SERVICE:** Select code for the hospital service with which the investigator is identified and/or from which salary is paid. If salaried from VA research funds, enter code 09, 13, 27, or 41.

10. **13 and 14. PRIMARY and SECONDARY RESEARCH INTERESTS:** Select codes that best define general areas of primary and secondary interests. Do NOT use 00 for primary research interest.

Revised: January 1997
### Project Data

Name: ___________________  
CID: ______  
Role: Principal Investigator

Project ID: 17777  
Project No.: 0040  
VACO No.: ______  
Project Status: Active

ACORP No.: ___________________  
IRB No.: 2001-762

Project Title: ______________________________________

Information above will automatically filled in

### Expenditure Data

Information below will automatically filled in. Except Amount Expended and Percentage effort.

**PI NEEDS TO COMPLETE AMOUNT EXPENDED AND PERCENT EFFORT**

1. 
   a. If Project is/was not funded (Funding Code 0000) and 1c. does not apply, skip to signature line.
   
   b. For Funding Code(s) not starting with "90", enter Amount Expended during current fiscal year. If funds were received from Center, Core, or Program Project Funds, enter only the amount that was expended during current fiscal year in support of your portion of the project. Do not enter Indirect Funds overhead.

   c. Funding Sources may be added or deleted (except Codes 9022, 9024, 9025). Do not list more than 3. If an added Code ends with "99", enter Name of Funding Source. If Admin Code is "08", enter Name of Administrative Agency.

   d. If any Funding Code starts with 91, 92, 93, 97, or 98 and you enter an Expenditure for the Code please complete Item 2.

<table>
<thead>
<tr>
<th>Code</th>
<th>Admin Code</th>
<th>Amount Expended</th>
<th>Name of Funding Source</th>
<th>Name of Admin Agency</th>
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<td>9143</td>
<td>06</td>
<td></td>
<td>Natl Inst of Health (Inst not known)</td>
<td>VA - Private Research Corporation</td>
</tr>
<tr>
<td>9399</td>
<td>06</td>
<td></td>
<td>Other Government or Academic</td>
<td>VA - Private Research Corporation</td>
</tr>
</tbody>
</table>

2. Extra-VA Funds include all Funding Codes starting with 91, 92, 93, 97 and 98. If you entered an Expenditure for any Extra-VA Funding Code shown above, please circle a number below that best approximates the Percentage of Extra-VA funded research that was performed at the VA.

<table>
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<th>%</th>
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02/05/2018

Signature ___________________  
Date ___________________
Re: Project 0010: What Makes Disneyland the Happiest Place on Earth?

The Research Service is required by the VA Office of Research Oversight (ORO) to ensure that all personnel who work at this facility on VA R&D approved research projects have currently valid VA appointments and have met all training and administrative requirements. Personnel not in compliance must cease work on all research studies until they have met all requirements. If the Principal Investigator is non-compliant, the study is subject to closure by the R&D Committee. Furthermore, submissions for both new and existing projects having non-compliant personnel can not be scheduled for committee review until all personnel are compliant.

Compliance data for personnel who have been designated as working on the above referenced project are shown below. If any listed person is no longer working on this project, please submit a modification to remove.

Non-compliance is indicated by cells with a red background. Date listed is the expiration date of the training.

<table>
<thead>
<tr>
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<th>Va_appt</th>
<th>Hst</th>
<th>Privacy</th>
<th>Labhaz</th>
<th>Infosec</th>
<th>Scope</th>
<th>Ethics</th>
<th>AGE</th>
<th>Ohs</th>
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This is what your spreadsheet should look like:

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Key is listed in footer (except AGE – Government - Ethics the Essentials (formally Annual Government Ethics):
Scope = Scope of Practice; VA_CITI = VA Human Subjects Training; Biosafe = GLA Biosafety Course; Biosec = VA ORD Biosecurity Training; Ethics = Responsible Conduct of Research; Infosec = VA Information Security Awareness; Privacy = VA Privacy Awareness; Amc = Admin Med Clearance; Wwi = Working with the VA IACUC.
1. This is to request leave without pay for a total of _______. I am requesting LWOP as I have exhausted my annual leave and will need to ________________________________.

2. I plan on taking the following hours of leave without pay, which has been recorded into the VISTA system:
   - MM/DD/YY - 8 hrs
   - MM/DD/YY - 8 hrs

Dean Yamaguchi
ACOS Research and Development
(signature required for requesting more than 2 days)