

OPERATIONS MANUAL Version 10/18/2021

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I. INTRODUCTION

The Veterans Health Foundation (VHF), the "Foundation", is a nonprofit 501(c) (3) corporation established under the Internal Revenue Code and 15 PA C.S. 5306 Pennsylvania Tax code Section as set forth in the articles of Incorporation recognized by the Commonwealth of Pennsylvania in 1991. The independent tax-exempt corporation was created to support research and education at the VA Pittsburgh Healthcare System (VAPHS). VA-affiliated Non-Profit Corporations ("NPCs") were established by Congress for the receipt and administration of research and education funds. The sole purpose of a VA NPC is to advance the research and education mission of the Department of Veterans Affairs through the support of approved research and educational activities as described in sections 7303(a) of authorizing title and education and training as described in sections 7302, 7471, 8154 and 1701(6) (B).

VHF is governed by a Board of Directors. The property and business of VHF shall be managed by its Board, who may exercise all such powers of the Foundation.

Mission Statement: The mission of VHF is to enhance the health and well-being of all Veterans by supporting and advancing research and education at VA Pittsburgh Healthcare System while observing the highest ethical standards and conducting all activities with honesty and integrity.

These policies are intended to serve as guidelines. No policy can anticipate every circumstance or question. As the Foundation continues to grow, the need may arise to change policies. Therefore, the Foundation reserves the right to revise, supplement, or rescind any policy, or portion of the guidelines, from time to time as it deems appropriate. Account holders and Foundation employees, as applicable, will be notified of such changes as they occur.

No policy of the Foundation shall be knowingly carried out if it conflicts with Federal, State, or local authority or common ethical principles. In keeping with this, no activities of the Foundation shall involve any personal benefit to those affiliated with the Foundation.

The Foundation Office should be contacted for any questions regarding these policies.

II. OVERSIGHT OF VHF

VHF is subject to federal oversight by the VA Secretary, the Inspector General, the Internal Revenue Service, and the U.S. Comptroller General. Pennsylvania State law governs its day-to-day operations. VHF is a member of the National Association of Veterans Research and Education Foundations (NAVREF).

The Foundation is audited annually by a professional external auditing firm. VHF's fiscal year runs from January 1 through December 31.

III. ACCOUNTS WITH VHF

A. ESTABLISHING AN ACCOUNT

Funds administered by VHF may only be designated in support of an approved research or education activity. These activities are performed by Principal Investigators (PI) in their capacity as VA appointees, with or without compensation (WOC. If a VA-paid appointee terminates VA employment, the individual must obtain a WOC appointment in order to continue the activity and maintain funds within VHF. Any PI interested in submitting federally funded grants must also hold a faculty appointment with a university. Investigators without faculty

appointments or investigators who are not in good standing must be reviewed and approved by the Executive Committee prior to submitting grants. The EC will in its sole discretion determine based on but not limited to professional reputation, academic history and prior research experience.

Research projects must have the appropriate committee approval. The Research Office maintains current application procedures/forms on their website. Projects sponsored by a for-profit company must also have a fully executed agreement in place prior to the acceptance of any funds.

Education activities supported by VHF must have approval by the Education Committee Special circumstances may be considered, such as donations or grants for a specific activity related to research or education.

VHF will establish an account upon execution of a new agreement or notice of award or upon receipt of funds. Funds will be in a holding pattern until documentation of the proper approvals has been provided.

Except in special approved situations, an investigator may have only one account with VHF for each funded project, and each project may be supported by only one unique account. VHF will classify active accounts as "temporarily restricted" or "unrestricted.".

B. TEMPORARILY RESTRICTED ACCOUNTS

Temporarily restricted accounts are for active research and education projects that have restrictions, activities, or deliverables tied to the funding. The PI is obligated to complete a task (e. g., a clinical trial) or produce a deliverable (e. g., a manuscript) with the funds. Expenditures made using a restricted account must be in support of that research or educational project as detailed in the budget agreement with the funding source. These funds may only be used to support the specific study for which they were intended.

C. UNRESTRICTED (RESIDUAL) ACCOUNTS

Unrestricted residual accounts are for funds that are no longer tied to contracted or awarded obligations and are the result of completed/closed research and education projects. All account funds are property of VHF. Projects are considered completed/closed when the investigator has fulfilled all obligations specified in the contract to the project's granting agency. If no refund is due to the sponsor or funding source, the remaining funds awarded are no longer restricted. The account is then classified as unrestricted. Expenditures made using an unrestricted account must follow VHF's guidelines referenced in this document.

Residual Accounts ending a fiscal year with less than \$250 of unobligated funds will be identified for closing. PI will be notified and given 90 days from the sending of the notification to expend the funds. Any residual accounts that remain open and under \$250 at the end of 90 days will have the remaining funds transferred to the Special Programs account and used at the discretion of the Board of Directors. If the PI maintains at least one active study at the Foundation, he/she may request that the residual funds account remain open until the end of the current active study so any future residual funds may be combined with the existing project.

D. DEPOSIT OF FUNDS

Funds may be accepted by VHF from a variety of sources, such as federal or private non-profit agencies, commercial organizations involved in medical research, charitable foundations, professional societies, or individuals. All checks should be made payable to the Veterans Health Foundation and mailed directly to our office. Cash deposits will not be accepted. Funds in VHF accounts are property of the Foundation and are not to be used for the personal benefit of any

investigator. All interest earned remains with VHF. Under no circumstances will payment in any form (cash, travel, gifts, and bonus) be made directly to the principal investigator, to any of the investigator's study employees, or to any other organization or party without prior written approval from VHF.

<u>Transfer from a Nonprofit</u> - Funds may be transferred from accounts at other VA affiliated nonprofit institutions. Indirect costs may have already been deducted. If they have, administrative overhead charges may be waived. Such exemption does not extend to funds in support of an active project being transferred; rather, project funds will follow the stipulations or guidelines of the funding agency or institution.

<u>Donations</u> - Any conditions to be imposed on the investigator and/or VHF in terms of how the funds can be used should be provided prior to sending funds. Funds will be accepted only if the Foundation determines the conditions can be met legally, ethically, and organizationally.

E. ACCOUNTABILITY OF FUNDS

It is the responsibility of the PI to ensure that all disbursements of funds from a specific source or granting agency are spent according to the guidelines established by that source or agency. Individuals may be held personally responsible if a commitment of funds violates the intent of funding agreement or contract.

The PI is also responsible for reconciling project statements provided by the VHF. The PI is to notify the Foundation of any discrepancies within 30 days of receiving the report.

F. DISPOSITION OF ACCOUNTS:

RETIREMENT, RESIGNATION OR OTHER SEPARATION FROM VAPHS

Upon departure of an investigator from VA, residual funds and equipment associated with that investigator may be retained by the VHF. Alternatively, such funds and equipment may be transferred, but only to another VA affiliated NPC or to a VA medical center, subject to approval by the Board and the recipient NPC or VA entity. Departing investigators may not transfer funds to other organizations such as Universities. If there is an ongoing VA approved research project linked to the account of an investigator who has left VA, the ownership of the account may be changed to a new PI as long as the change in PI is approved by the appropriate VA Research subcommittee (IRB, IACUC or RSEC subcommittees). Residual funds in the accounts of investigators who are leaving VA may not be transferred to other investigators but will be transferred to VHF's Special Programs account. If equipment is not transferred to another VA NPC or VAMC, it may be reassigned for use by another principal investigator, research group, center or core function by direction of the Chief Executive Officer (CEO).

G. OVERDRAWN ACCOUNTS

Except for federal awards, overdrafts will not be permitted. Should an investigators account become negative, after accounting for accrued revenues and salary expenses, the investigator will be required to provide a reason for the deficit and the actions implemented to correct the deficit and prevent future deficits. Investigators are solely accountable for the financial sustainability of their projects.

H. DORMANT ACCOUNTS

A dormant account is an account that remains inactive for 24 months. Investigators with dormant accounts will be given a notice detailing the inactive account status on no less than an annual basis. Within 30 days of the notice, Investigators must provide VHF with a detailed written plan for reactivating the account. If no such plan is provided, or the plan is not approved, the account will revert to the VHF Special Programs fund. The Chief Executive Officer has full discretion to approve or deny spending plans. Investigators will be notified of the transfer via a courtesy phone call. Accounts with no activity will be charged 3% of the available balance on an annual basis.

I. CLOSED / COMPLETED ACCOUNTS

When all project related activity has been completed and all deliverables and other contractual obligations have been satisfied the project may be closed. As a final action, the PI needs to complete and send the Project Closeout Form to VHF.

J. ACCOUNT REPORTS

Summaries of all transactions (deposits and expenditures) for each active account will be provided on no less than a quarterly basis. Investigators may request statements on a more frequent cycle. The report provides a summary of all transactions from project initiation through the reported month.

IV. EXPENDITURES

A. ALLOWABLE EXPENSES AND RESTRICTIONS

- **1. Books/Publications** —With a direct relation to VA research and/or education.
- 2. Business Meetings Meetings, conferences, workshops, seminars, grand rounds, symposia, and other similar events are accepted components to a robust research and education program. Additionally, certain events, such as retreats, may be necessary for the conduct of business.
- 3. Meals and Refreshments Incidental to the business purpose of such meetings, it may be appropriate to serve meals or refreshments. Various regulations, the federal ethics standards, and the statute that authorizes VHF influence whether expenditures related to such events are appropriate for VHF support. In order to be eligible for VHF support, a meeting must have a documented research, education, or business purpose. VHF will not support "entertainment" expenses such as social activities, parties, ceremonial occasions or those that provide amusement. Consequently, in order to be considered for VHF support by direct payment or reimbursement, VHF has established the following policy:

Approved Uses:

- VHF business meetings
- VHF Fundraising events
- In association with recruitment of a new clinician/investigator
- Special events, such as award presentations or lectures that include both non-VA and non-VHF employees.
- Infrequent VA staff, committee, or department meetings that further the VA research and education mission.
- Prolonged (>2 hours) meetings, meetings that extend beyond or occur outside of the normal tour of duty, or meetings occurring over the lunch hour that serve an education

or research purpose. These meetings should be advertised at the participating VA institution via email or through other public notifications.

Prohibited Uses:

- Refreshments/meals for routine VA staff, committee, or department meetings
- Refreshments/meals for staff holiday parties, retirement parties, or other celebrations
- Any entertainment cost not described above.

For a research related program:

- A request for VHF support must include an explicit statement about the research rationale for the event, that is, its research related purpose and how it will further VA research.
- Accompanying documentation should include the program, agenda, or topic of discussion.
- When appropriate, the request should tie the meeting to an approved research project.
- Must be widely advertised to participating VA organizations via email or other public notice.

For an educational program not related to research:

- The education activity must first be approved by the ACOS for Education or the designated learning official.
- Documentation should include an explicit statement of the purpose and how the program will further the VA's education and training mission, the agenda, program or topic of discussion, meeting location, presenter(s), roster of attendees and each attendee's organizational affiliation.
- Must be widely advertised to participating VA organizations via email or other public notice.

For other appropriate VHF business events, which include but are not limited to, retreats and recruitment dinners for prospective appointees:

- A request must include an explicit statement of how the meeting will further VHF's ability to facilitate research and education.
- Documentation should include the purpose, agenda, program or topic of discussion, meeting location, presenter(s), roster of attendees, and each attendee's organizational affiliations.

Requests for VHF support will be reviewed and approved by the CEO. VHF will either provide direct payment or reimbursement based on submission of original receipts. Non-detailed credit card receipts are not sufficient documentation for reimbursement. VHF requires that meeting organizers obtain pre-approval of VHF support for meals and refreshments. Events lacking pre-approval may be denied support or may receive only partial support. Pre-approval may be obtained by submitting the completed "Request for Meals or Refreshments" to VHF office staff. Requests must be made at least two weeks in advance prior to the meeting or event. Funding requests which exceed \$1,000 must be made at least 30 days in advance.

4. Personal Use Devices

Cell Phone Service/Personal Use Devices - It is the policy of the Foundation to support technology required in the performance of approved activities while simultaneously assuring that "private benefit" does not jeopardize VHF's non-profit status or the

individual's tax liability.

Home Use - VHF will not purchase or reimburse for any goods or services that are purchased for the personal benefit of an individual. Equipment such as personal computers and peripherals that are purchased for home use are assumed to be for the personal benefit of the purchaser and will not be authorized for purchase or reimbursement without written affirmation from the purchaser that the equipment is to be used solely for VA approved research and is not for personal use.

- **5. Conferences** Requests may be approved to organize a conference which carries out the educational and research mission of VHF and/or VA. VHF may contract with sponsors for support and fund raising to cover the cost of the conference. VHF may contract for services necessary to implement the conference and associated activities. Attendee registration and fee payments may be administrated by VHF. Educational conferences are allowable when approved by the Education Committee.
- **6. Personnel** —The hiring of personnel must be managed by VHF Administrative personnel. VHF is the employer of record and is responsible for all human resource activities. The CEO has final approval on the hiring of all personnel.

Process Overview for Hiring Personnel

- Investigator or designee contacts VHF Administration and expresses the need to hire staff. A review of available funds will be done to determine how the position will be funded. If an employee is hired based on project specific funds and that project loses those funds, the position will be terminated. Funds must be available to support at least 6 months' worth of salary and fringe.
- A completed Request to Hire Form is required. All requests must include a position description (in the required format) and the candidate's CV or resume if a candidate has already been identified. Please utilize an existing PD if available. PDs are not meant to be project specific.
- All VA employees supervising a VHF employee must complete supervisor training through VHF.
- Only the Chief Executive Officer or designee may initiate an offer of employment. Upon acceptance of an offer, the employee will be contacted by the VA Research Office to initiate the Without Compensation (WOC) process if one is not already in place.
- Completed WOC applications are forwarded to the VA Office of Human Resources. An employee may not begin working until a WOC appointment has been granted and the Welcome Letter has been received. Licensed individual Practitioners engaged in human subject's research are also required to have their professional credentials verified before they can initiate human subjects research.

7. Employees Working on an Intergovernmental Personnel Agreement (IPA)

IPAs are agreements pursuant to the Intergovernmental Personnel Act which provides a mechanism for the Federal Government to share staff across institutional boundaries and provides for the temporary assignment of personnel in positions that require specific skills. IPAs are most commonly implemented to allocate VHF or University employees to VA funded projects. All employees must submit a timecard to appropriately document time being loaned to the specific project(s).

The IPA mechanism **may not** be used under the following circumstances:

To circumvent federal hiring practices or contracting policies or procedures.

- To hire clinical staff or as a substitute for scarce medical specialists, sharing, commercial item or other clinical services contracts
- For administrative or support positions
- To facilitate career change
- For a temporary employee, including post docs and others in training positions (and in the case of a VA employee, those with limited time appointment)
- PIs may not be placed on an IPA.

Terms of an IPA Agreement:

- Approval covers the start date of the initial assignment through a period of exactly 2 years later.
- No agreements may be more than 4 years.
- Extensions may be requested for any period not to exceed 2 years. No agreement may be approved for more than a total of 4 years.
- Assignments may be made on an intermittent, part-time, or full-time basis. The investigator or hiring manager must have sufficient funds within VHF to support the first 6 months days of salary and fringe. The status for the first 90 days must be consistent with the remaining term of the IPA.
- A 12-month break in service is required between assignments of 4 consecutive years. Federal employees are subject to a 6-year cap on IPA assignments for life of Federal career (OPM may waive justifiable cases at VA's written request).
- IPA Assignment Agreements must be submitted at least 30 days prior to the effective date to assure seamless implementation at the desired IPA start date.
- A CV/resume and position description are required if not already on file.
- All VA requirements must be met prior to the IPA start date. This includes a WOC appointment that must cover the IPA appointment period. If the WOC is scheduled to expire prior to the IPA appointment period, either the IPA or WOC appointment must be adjusted.
- Per employee, all new IPAs will be billed a minimum \$500 administrative fee, which will be billed the 1st month following IPA initiation. The initial \$500 fee will offset the standard 3% fee of the total direct IPA cost. Only when the cumulative 3% fee exceeds the initial \$500 fee will the 3% administrative fee be applied. Administrative fees will not exceed \$3,000 per employee in a fiscal year. PIs must cover this fee with administrative or other unrestricted funds. This fee cannot be billed to the IPA.

Special attention must be made to the entries for the "Reason for Mobility Assignment" and the "Position Description" sections to demonstrate the scientific, technical, or hard-to-fill nature for the position.

Individuals who are on an IPA must follow the federal ethics rules and the federal conflict of interest statutes. (OPM Mobility Program). Also, said individual shall abide by both the VA and VHF rules and regulations. IPAs shall not be modified, except for administrative errors, and will not include travel costs for seminars that are tertiary to the IPA assignment. However, travel will be included in an IPA if it is necessary to disseminate scientific results from performing VA research. All increases in salary must be justified and shall only be made on the IPA's annual renewal unless a special award is requested and justifiable. If an award is being requested outside of an annual renewal, a completed Request for Special Contribution Award must be completed and submitted.

Once the IPA is effective, VHF office staff will begin the billing procedures and prepare the invoices for approval and processing through the federal government's electronic invoicing

system. On a monthly basis, office staff will review the complete IPA roster to determine continuation of the agreement and to alert the PI as to the ending date of the IPA. The PI is notified 90 days prior to the end date with a request for a plan for the continuation or termination of the employee.

8. Dual Compensation of VA employees

Part-time or full-time VA employees <u>may</u> be hired by VHF in a role that <u>differs</u> from their VA role. A "Justification of Joint Appointment" Form must be submitted for review. The Executive Committee must approve any request for dual employment. All requests will require an ethics opinion from the VA Office of General Counsel. VA employees may <u>not</u> work for VHF during their VA tour of duty. Any salary or wages earned as a VHF employee must be for hours worked <u>outside</u> of the VA tour of duty and for duty <u>different</u> from the individual's VA work.

If a VA employee is hired as a VHF employee, appropriate records must be maintained to document the absence of conflict between VHF supported work and VA duties. These records will include a VHF and VA position description outlining anticipated duty hours and responsibilities. If a conflict arises between the two positions, the employee will be terminated by VHF.

An investigator may not in any way supplement the salary of a VA employee by means of performance awards or bonus payments.

- **9. Donations to Other Organizations** VHF funds **may not be used** for donations to other organizations. Payments may be made to another nonprofit corporation in support of an approved research or education activity.
- 10. Equipment Items classified as equipment include physical assets that are used on an ongoing basis in a laboratory or office including: machines, furniture, and some types of computer software. It does not include consumable supplies. For example, a laser printer is classified as equipment, but toner cartridges used in the printer are not. VHF classifies fixed asset purchases of \$2,500 and over as equipment, anything less than that is considered supplies (generally reported as Equipment under capitalization threshold). The classification is also based upon use and ability to be consumed. VHF will not purchase equipment unless it is supported by VA. Equipment purchased by VHF becomes the property of VHF, unless it reverts to the sponsor upon completion of a research project; therefore, the Foundation retains the right to dispose of the purchased equipment if not required to be returned to the sponsor. All equipment owned by the VHF will be identified with a VHF tag and inventoried annually with records maintained on the location and assignment. All computer and computer equipment must be inventoried annually regardless of value. Any transfer of equipment must be approved by the CEO.
- 11. Gifts or Contributions Tokens, pins, certificates, etc. of negligible value which are given to patients or employees during the course of a research activity/event or attendees at an educational program related to research are generally allowable. Gifts to VA employees cannot exceed \$20 per source at any one time, but no more than \$50 in a calendar year from the same source.
- 12. Independent Contractors/Consultants— A consultant/independent contractor is a person hired to perform a specific task, with the institution having no right to supervise or control the manner or means by which the task is accomplished. Independent contractors may be paid a fixed sum per completed task or may be paid on an hourly basis. An independent

contractor is not entitled to the protections and benefits of employment. A contractor uses his/her own equipment and tools, can hire assistants, makes services available to the public, and his/her work may result in a profit or loss. In general, VA employees are not eligible for Consultant fees. An investigator may not hire a family member. A Form 1099 is submitted to the contractor/consultant and the IRS for payments of \$600 or more.

A request for approval to hire a consultant must be submitted to VHF Administration prior to any work being offered. This request must indicate the specific service to be provided and the fee to be paid.

Guidelines:

The following guidelines apply in securing the services of an Independent Contractor, including a Consultant:

- A person may not be engaged as an Independent Contractor in lieu of being hired when an Employer-Employee relationship exists.
- Classification of status as an Employee or Independent Contractor must be made prior to an engagement to perform personal or professional services.
- No payment will be made for services performed prior to execution of a Contractual Services Agreement.

The following additional requirements apply to the appointment of a Consultant:

Arrangements to secure the services of an Independent Consultant may be entered into
when a determination has been made that the services are so urgent, special, temporary
or highly technical that they cannot be performed economically or satisfactorily by
existing VHF staff during the course of their normal duties.

Services of Independent Consultants paid for by federal funds are normally limited to not in excess of 30 days in a 12-month period, or the period of time which is set by the cognizant contract or grant. In addition to the time element described above, federal auditors use the following standards in support of the use of Consultants on federally funded projects:

- There must be evidence that the services are essential and cannot be provided by persons receiving salary support under the federally funded project.
- There must be evidence that the person selected is qualified. A curriculum vitae or similar documentation must be submitted with this agreement.
- There must be evidence that the rate is appropriate considering the qualifications of the Consultant, his/her normal rates, and the nature of the services rendered.
- An Independent Consultant shall not be used to carry out a major portion of a program.
- Services of an Independent Consultant shall not entitle the person to credit other than as a "consultant" in any published report or other document.
- Any changes, extensions or increase in the scope of work, shall be handled by a brief memorandum to VHF's administrative office.
- VHF has no obligation to withhold income or FICA taxes on amounts paid to Independent Contractors.
- If payments to an independent contractor accrue to \$600 or more during a calendar year, payments will be reported on IRS Form 1099-MISC.
- No family member of a Principal Investigator may be engaged as an Independent Contractor by that Principal Investigator.

To initiate a Contractual Services Agreement for a Consultant, please determine the relationship. Determine if an independent contract relationship should be established following IRS Guidelines. In recent years, the Internal Revenue Service (IRS) has sought out and imposed severe penalties on companies that treat employees as Independent Contractors, and which fail to withhold taxes. To avoid the paperwork

burden and expense of payroll taxes, some employers inappropriately designate workers "independent contractors." If the IRS determines that the worker is an "employee," the person responsible for the collection and payment of withholding taxes may be held personally liable for an amount equal to the taxes that should have been withheld.

The process to determine an independent contract relationship begins with submitting a written request to VHF Administrative Office detailing the proposed agreement: the name of the contractor, contact information, Federal Tax Identification Number, the services to be provided, the amount to be paid and the term of the agreement.

- VHF will draft a contract and work with the contractor to have it executed.
- VHF will scan the contract into its shared file of CSAs and provide the investigator with a copy of the executed contract.
- Upon completion of the contract and verification that all deliverables and tasks have been completed, the IC may submit an invoice for payment. The invoice should refer to the assigned project number if applicable and include all pertinent information requested above.

If documents are not received in advance for VHF preparation or review; payment may be refused.

13. Laboratory and other Clinical Expenses

Expenses for Offsite Offices and Laboratories — Special situations may require research activity off-site. Prior approval must be obtained for any expenditure requested to support off-site activities. Submit a written request to VHF describing the specific project and activities to be conducted off-site. The request should include a detailed budget for the off-site expenses and a justification as to why the activities cannot be housed on VA grounds (i.e., VA is unable to provide space for the activity).

<u>Clinical Care/Procedural</u> —Funds may be used to reimburse VA for clinical costs which are deemed to be research procedures. All MOU's and/or support letters must be routed through VHF for approval.

14. Licenses / Exams —VHF funds may not be used to support VA employees' tests for certification in medical practice, professional license fees, technical certifications, or medical board certification. Specifically, board exam costs, state license fees, DEA fees, may not be paid. Expenses related to professional licensure (annual fees, board certification courses, etc.) are also not allowable, regardless of source of support.

Certification/licensure fees *may* be paid for VHF employees.

Tuition payments or registration fees may be paid for courses that directly relate to the activities of an approved research or education project. Examples include courses on statistical analysis of research data or on programming computer databases

15. Registration — Payments may be made for registration fees associated with continuing education or professional organization activities. This only applies to non-degree courses that are directly related to the research or education activities of the investigator or research staff. Pre-approval is required, and reimbursement will be withheld until receipt of supporting documentation.

16. Recruitment — Reimbursement may be requested for expenses incurred by a VHF applicant and spouse for an interview trip, if the applicant is being recruited for a position that will enhance the mission of VHF. Reimbursement for the applicant's spouse is acceptable since it provides an opportunity to survey the housing market. The payment of spousal expenses applies to only one interview trip. A maximum of 3 days of expenses will be reimbursed. Expenses will include coach air travel, per diem, lodging and car rental. All expenses must be properly documented, and original receipts are required.

17. Payments to Research Participants —

Payments to research participants include stipends for participating in studies and direct payments for expenses of study participation, such as travel reimbursements. VHF support letters must be submitted to VHF Administration along with a copy of the final approved budget. Documentation of the research project approval by the Institutional Review Board (IRB) is also required before issuing payment to a research subject. Payment will be made in accordance with an IRB approved informed consent document. Subject stipends are taxable income. All subjects will be required to complete a W9 form. VHF is required to report stipend payments totaling \$600 or more in a calendar year and will issue IRS form 1099 to qualifying payees. VHF has adopted the ClinCard subject compensation system which provides pre-paid credit cards to patients in lieu of check payments. This system provides faster compensation to the subjects and enables better reporting and oversight of the compensation procedures. All VHF administered projects must utilize the ClinCard system; however, there are circumstances in which check payments may be authorized (e.g. one-time payments, studies in which the subjects are never seen at the site). Use of check payments requires prior approval by the CEO. Requests for a check payment must be made to the VHF office by completing the "Participant Check Payment Request" form. PIs may approve each request or assign a designee as approver of payment requests.

- **18. Payment to Speakers** Payment to a speaker is an honorarium and will be reported to the IRS as income as required. A complete W-9 form is required when applicable.
- 19. Personal items Personal services will not be paid through VHF. Personal items (clothing, grooming, etc.) will not be paid. No expenditure will be authorized for personal housing expenses, business use of personal residence, health or social club dues or initiation fees, or personal services (maid, chauffer). Reimbursement requested for items shipped to a non-VA address such as a home address will be considered personal items and will not be reimbursed.
- 20. Subscriptions & Memberships Subscriptions or professional association dues, with the exclusion of license fees, may be paid from appropriate research or education accounts. Upon approval, all dues and subscriptions should use the VA address. Organizational memberships cannot be paid using VHF accounts unless that membership is necessary to receive the organization's journal or publications. Renewals can only be made for one year at a time. Investigators must indicate in what way the publication, subscription or membership impacts/benefits the specific research or education project. Professional membership fees may be paid in a situation in which an employee of VA or VHF is required to join the organization to serve as the official representative of VHF to that organization.
- **21. Supplies** —Supplies may be purchased with reasonable rationale provided. All animal orders require approval by the ARF supervisor in advance to ensure project has been approved and that space is available.
- 22. Travel VHF funds may be used to support travel expenses associated with furthering or

facilitating appropriate research or education activities unless otherwise restricted or obligated. Travel is a necessary part of research activity. It is also one of the areas closely scrutinized by auditors and oversight agencies.

All travel must be pre-approved. All travel requests (including supporting documentation) must be received at least four weeks prior to intended departure in order to allow sufficient time for approval, unless extenuating circumstances exist which necessitate a shorter pre-approval period.

Guidelines and Requirements for VHF support of travel

- <u>Acceptable Travel</u> Travel to research meetings of clinical specialty societies, research societies, national and international general clinical groups (AMA, WHO) that have recognized or stated primary goals which are to further medical knowledge, research, public health and/or education are acceptable when the proposed travel has a demonstrable research relevance or is related to an approved staff or patient education activity.
- Relevance It is the responsibility of the traveler to submit adequate documentation to justify a primary purpose of supporting their research/approved education activity/administration activity. If the travel is strictly for educational purposes, it must be documented as being work-related instruction to improve performance of duties; maintain or increase specialized proficiencies; or expand understanding of advances or changes in patient care, technology and health care administration.
- Acknowledgement of Institutional Affiliation VHF was established to support VA
 research and education. Accordingly, the Board of Directors has authorized the denial of
 support for travelers who fail to appropriately acknowledge the VA and VHF institutional
 affiliation. Failure to give primary identification to VA and VHF can be harmful to the
 agency and future funding opportunities. The traveler's VA affiliation should be identified
 appropriately in conference brochures, name tags, attendee rosters, etc.
- Approval Authority Approval of travel related expenses resides with the CEO. Exceptions to stated policy may be made only by the CEO or the Board of Directors. A fully completed "VHF Travel Authorization Request" form must be submitted to the VHF office staff at least four weeks prior to departure. The travel request should be completed with everything the traveler wants to be considered for reimbursement and submitted with supporting documentation. Requests for travel must justify the research or education relevance of the travel. Approval of all travel requests hinges on an appropriate justification being provided. A copy of the program or conference announcement must be provided. In addition, travelers making presentations must include a copy of the invitation or acceptance letter. VA employees requesting VHF travel support must also submit a completed and fully signed VA Form 0893 – "Advance Review of Offer to Donate Support for Official Travel" This form must be attached to the Travel Authorization Form along with an approval memo from the Chief of Staff's office for consideration of VHF supported travel. Following approval, the traveler will be notified so that they may begin to make arrangements. VA imposes special requirements for foreign travel for VA-paid employees. VA-paid employees are responsible for complying with these requirements.
- <u>Travel Status</u> VA employees must be on approved VA travel status to receive reimbursement for travel expenses. Reimbursement will not be made for travel conducted on annual leave. Exceptions will only be made by the Executive Committee.
- <u>Advances-</u> No cash advances, reimbursement, or pre-payment will be made prior to the date of actual travel. Meeting registration fees may be requested in advance and will only be

made payable to the organization sponsoring the meeting. Exceptions to this policy must be pre-approved by the CEO.

- <u>Transportation</u> Maximum transportation reimbursement shall be limited to the most economical mode of transportation and the most direct or customary route. Transportation costs may not exceed economy class fare by airplane or train. If an indirect route is traveled for personal reasons or if travel by direct route is interrupted, the traveler will be responsible for any resulting incremental expenses. No cash advances or reimbursement of transportation tickets will be made prior to the date of the actual travel. Ground transportation will be reimbursed at cost based on submission of original receipts. Reimbursements are limited to travel to and from the city-of-departure airport/train station plus parking; from airport/train station to hotel, and hotel to airport/train station. A receipt is required for parking charges. In addition, a receipt is required for all cabs over \$5.00. Once the traveler has arrived at the hotel, transportation costs will not ordinarily be reimbursed (to go out for dinner, etc.). Because meeting hotels are generally within walking distance or provide free shuttle service to the conference site, any fares requested will require a separate justification attached to the traveler's reimbursement request. These exceptions will be reviewed and approved by the CEO on a case-by-case basis. In certain cities, use of a rental car may be authorized, but only if approved in advance by the CEO.
- Rental Cars Rental cars may be used only when such rental is justified as being more advantageous to VHF than the use of other means of transportation. Midsize or smaller cars should be rented. When renting a car, the traveler should elect to take insurance offered by the rental car company. (If the traveler foregoes such insurance any liability will accrue to the traveler.) Legible receipts for gasoline purchased for use in rental cars must be included if that is claimed as reimbursement. It is the traveler's/requestor's responsibility to provide a cost comparison and justification as part of the request.
- <u>Air Travel</u>— Economy class shall be used. The exception for use of upgraded service for medical necessity requires approval of the CEO on the "Travel Authorization Request Form." The cost of canceling and rebooking flights may be allowable if it can be shown that such was necessary for legitimate business reasons, illness or other compelling circumstances. It is the responsibility of the traveler to cancel reservations that will not be used. Charges or forfeited refunds from failure to cancel in a timely manner will not be reimbursed.
- <u>Baggage</u> Baggage includes both the traveler's personal property and any VA or VHF
 property. VHF will reimburse for one checked bag round trip. Excess baggage charges may
 be allowed if justified by an explanation of the circumstances and provision of a legible
 receipt for such charges.
- <u>Stopovers and Deviation</u>- If a traveler chooses to deviate from the most cost-effective itinerary that meets the needs of the trip, any additional cost will be considered a personal expense. In some cases, there is a cost savings when a traveler deviates from the business itinerary. The cost savings may not be used to reimburse the traveler for expenses that are personal or do not have a business purpose.
- <u>Use of Private Automobile</u> Use of private automobiles must be approved in advance by the CEO. When authorized, reimbursement will be made at the prevailing federal mileage reimbursement rate plus applicable tolls. In no case will reimbursement for use of private automobile exceed the coach fare to the location in question. Actual odometer readings or MapQuest (or equivalent) mileage estimates will be required for reimbursement. The current federal mileage reimbursement rates can be found at www.gsa.gov.

- Hotel Accommodations-Travelers will be reimbursed for reasonable hotel room costs as determined by the meeting site and prevailing hotel rates. Travelers should substantiate their room rate with program material detailing prevailing rates. The original itemized hotel bill must be submitted with the reimbursement request. Hotel reimbursement will be for days of the meeting and the evening prior. The night of the last meeting day will be paid if the meeting ends too late for a reasonable return flight. Reimbursement will be made for reasonable laundry and dry-cleaning costs if the hotel stay is five nights or more.
- Meals and Incidentals (M&IE) In accordance with an IRS accountable plan, meals and incidentals will be reimbursed at the prevailing federal per diem rate for the destination city. No receipts are required. This rate can be found at www.gsa.gov/perdiem. Per Diem allowances will be limited to the days of attendance at the conference plus the actual travel time required to reach the conference location by the most direct route. Where meals and/or lodgings are furnished without charge or at a nominal cost (as part of registration) this will be taken into account in calculating per diem allowance. Per Diem for the first and last day of the trip is reimbursed at 75% of the M&IE rate. Claims for 100% M&IE on the first and last day of travel must be requested and pre-approved as part of the travel authorization request. For example, a flight itinerary departing 6 am, returning 10 pm would be sufficient documentation to request 100% per diem on both first and last travel days.
- <u>Cancellations</u>- It is the traveler's responsibility to cancel any reservations that will not be used. Charges or lost refunds resulting from failure to cancel reservations will not be reimbursed unless the traveler can show that such failure was due to circumstances beyond the traveler's control.
- <u>Foreign Travel</u>- Foreign travel will be evaluated on a case-by-case situation. Existing VA regulations or approvals, passport and visa requirements will apply to all approved foreign travel. Travel in conjunction with a vacation will require extensive justification and may be determined to be personal benefit.
- <u>Spouse/Partner Travel</u>-Travel expenses incurred for spouses, children and companions will not be reimbursed. The cost of a shared hotel room need not be allocated between traveler and spouse/partner. If a room is upgraded for spousal/partner use, additional expense above approved rate is not reimbursable.
- Consultant/Subject Travel-Charges to a project for consultant costs may include fees and
 travel costs including transportation and per diem costs. Prior approval is needed for
 consultant travel charged to a sponsored award. Reimbursement of subject travel must be
 pre-approved by the sponsor and included on the consent form. In cases where a subject is
 entitled to mileage reimbursement, the subject must provide documentation of miles
 traveled to receive reimbursement.
- <u>Local Travel</u>- VHF will provide reimbursement for local travel to workshops, seminars and symposiums based on the following rules:
 - 1. Per Diem allowances must be reasonable and must be limited to the days of attendance plus the actual travel time required reaching the location by the most direct route available. Please refer to the per diem rate allowances. Actual parking costs are also reimbursable.
 - 2. In cases where meals and/or lodging are furnished without charge or at a nominal cost (e.g. as part of the registration fee), this will be taken into account in determining the per diem allowance. For example, if breakfast is provided the traveler should indicate

as such.

3. Mileage may be reimbursed for local travel to workshops, seminars and symposiums. Local travel is defined as a distance between the traveler's home and workshop which is less than or equal to the distance between the traveler's home and work location. If the distance traveled to the workshop is greater, than the traveler will be reimbursed for the mileage difference.

C. HOW TO REQUEST PAYMENT OR REIMBURSEMENT

Since research activities occur in a dynamic environment and projecting future needs may not always be possible, individuals may need to purchase necessary research relevant items and request after-the-fact reimbursement. However, every effort should be made to use purchase orders and have purchases paid directly by the Foundation. An example of appropriate use of reimbursement would be taking advantage of meeting discounts offered for on-site purchase of publications. Reimbursement should be limited to purchase of small supplies necessary for a project. The Foundation will not guarantee reimbursements for acquisitions that have not been reviewed and authorized prior to purchase. VHF will not reimburse any individual for the unauthorized purchase of goods or equipment that will be stored anywhere off VAPHS property. Any exception to this policy must have the written approval of the CEO before the purchase is made. Any equipment approved for off-site storage must be personally inspected and tagged. In accordance with Internal Revenue Code Section 62(c), employees must substantiate all business-related expenses to the Foundation within a reasonable time (no more than sixty (60) days from the date of the expense). Additionally, employees must refund to the company any excess advances within a reasonable period (no more than 120 days from the date of incurring or paying the expense) – no advances can be made more than thirty (30) days prior to the time of the expense.

If the Foundation accepts the justification for late submission and does not deny reimbursement for requests submitted after the sixty (60) daytime frame, the reimbursement must be reported as taxable income to the employee. Therefore, it is critical that requests for reimbursements are submitted as expeditiously as possible.

It is the policy of the VHF that any requests for reimbursement of expenses which are more than ninety (90) days old will be denied.

Requests for travel reimbursements must be submitted to VHF office staff using the "VHF Travel Reimbursement" form and must be accompanied by required documentation, legible receipts and justification for the expense as outlined in the travel policies. Please note that if travel costs are to be divided between VHF and VA or the University , a copy of the VA and/or the University travel report must be included.

Requests for reimbursement of other business-related expenditures must be submitted to VHF office staff using the "Request for Payment/Expense Reimbursement" form. The completed form must be accompanied by the required documentation, legible receipts and the justification of the expense. This expense must follow the guidelines for reimbursable costs as outlined in Section IV (D).

A reimbursement check will be returned to the requestor within fifteen (15) business days, along with an explanation of any denied expenses, if applicable. Appeals of denied expenses must be submitted in writing to the CEO within a time frame which accounts for the sixty-day time frame limitations as previously discussed.

All orders must be shipped and delivered to the VHF office. Exceptions will be made for large

deliveries and deliveries of animals and/or chemicals. All invoices and shipping documents are to accompany the shipment.

VHF has established accounts with certain vendors. Use of these accounts can eliminate duplicate paperwork and, in most cases, it will reduce the amount of time for the delivery of the needed product.

Receipts are required for all reimbursements. VHF does not make payments to credit card companies. VHF will reimburse the individual. Submit a copy of the canceled check (front & back), when requesting reimbursements that were paid by check. As we are a tax-exempt organization all efforts must be made to utilize our purchasing agent as to avoid the costs of sales tax. Repeated requests for reimbursement with sales tax will be denied.

Fiscal Year End: Foundation's fiscal year ends December 31. All requests for expense incurred during the current year must be submitted by December 15 to meet years end financial close of the books. Expense request after December 15 may be booked in the new fiscal year.

Clinical Trials Center (CTC) Assessments- CTC assessments represent the fees assessed against revenue received by projects which choose to utilize the resources offered by the Clinical Trial Centers. This fee is assessed by the CTC and is intended to cover the payout of all allowable costs incurred to conduct each study. The CTC assessment for all patient participation revenue is 70%; however, the CTC recovers 100% of the costs associated with project start-up and regulatory fees. All revenue received for federally funded clinical trials will remain within the CTC after indirect costs are collected. The PI is not permitted to carry a residual balance on a federally funded project. All fees are subject to change as necessary in order to maintain the level of service provided by the CTC. (Note that the project will reflect the income from the funding sources and the assessment to that project will be shown as an expense item). This assessment is recognized as CTC revenue upon invoicing the funding source.

V. INVESTIGATOR ACCEPTANCE OF HONORARIA OR SPEAKER FEES

VHF will not accept honoraria provided to an investigator as payment (such as for speaking fees, writing fees and consulting fees), for participation in an activity as these potentially poses ethical problems, may impose an unexpected tax liability on the donor, and requires VHF to guard against use of the funds in ways that create an actual or perceived personal benefit for the donor. Investigators are strongly encouraged to contact Regional Counsel before accepting any payments. If an investigator or other recipient of such a payment wishes to make an unrestricted donation to VHF, that person should accept the payment personally, pay the applicable taxes and then make a personal charitable donation to VHF. If you have questions, please reference the Payment of Honoraria Decision Tree.

VI. EXTERNAL FUNDING

External funding primarily comes from two sources: commercial companies and granting agencies (Federal and Private). Either source may initiate contact with VHF or the PI to start the award/contract process, or the PI may seek out funding opportunities by identifying a Request for Proposal (RFP), open announcements or self-soliciting for funding a proposal.

A. OUTSIDE INITIATED CONTACT

Investigators may be asked to complete a questionnaire in order to gauge our suitability for a proposed study. Prior to receipt of the protocol a Confidentiality Disclosure Agreement (CDA) is typically required. All CDAs must be managed by the Grants and Contracts Manager. Investigators are not authorized to bind the VA in a CDA. If the PI is interested in the potential

research project, the PI should contact the CEO to discuss the CRADA and budget review process. Budget negotiations will be handled by VHF's Grants and Contracts Manager. The submitted budget will be reviewed for appropriateness of expenses and to ensure all costs are covered for the life of the study. The budget will be used to track spending during execution of the study.

B. FUNDS DONATED FOR EDUCATION AND SCHOLARLY ACTIVITIES

The VHF may accept and/or administer funds donated to the VHF if said funds are used to support education and training activities as outlined below. The support and the amount of funds received must be reasonable and appropriate for the proposed activity. Any items purchased as part of an approved activity are the property of the VHF and must be returned to the VHF upon completion of the educational activity or upon separation or termination of the employee. All expenditures must follow the pertinent VHF policy.

1. Permitted Uses

VHF may expend funds used for the following education and training activities for which there is no associated VAPHS-approved research:

- Educational seminars consistent with the mission of the VHF/VAPHS.
- Appropriate employee education and training activities consistent with the mission of the VHF/VAPHS.
- Patient education and training activities consistent with the mission of the VHF/VAPHS.

2. Prohibited Uses

VHF may not support the following activities:

- Any expenditure that is contradictory to any other existing VHF policy or procedure (e.g., purchase of a first-class ticket to travel to an approved educational meeting).
- Funds that are designated for an investigator or VAPHS Staff's account within VHF that are entirely designated as "Unrestricted" Funds.

For the purposes of the policy the term "education and training" refers to the following: In the case of employees of the Veterans Health Administration, the term means:

- 1. Work-related instruction or other learning experiences to:
 - a. improves performance of current duties;
 - b. assist employees in maintaining or gaining specialized proficiencies; and/or
 - c. expand understanding of advances and changes in patient care, technology, and health care administration.
- 2. Instruction or training conducted as part of a residency or other program designed to prepare an individual for an occupation or profession.

In the case of Veterans under the care of the Veterans Health Administration, such term means instruction or other learning experiences targeting patients and/or families and guardians of patients related to improving and maintaining the health of Veterans.

Requests for VHF support of education and/or activities must be submitted to the VHF using the form "Request for Review and Approval of Acceptance of Funds Supporting Scholarly Activities" form. Supporting documentation with sufficient detail must be submitted in addition to the form.

The Education Committee is charged with reviewing requests to ensure that said funds are being used to support educational activities as outlined above. Requests will be reviewed on an as needed basis and will be relayed via e-mail. Some requests may require an in-person meeting. The Education Office may recommend approval for use of funds in accordance with the permitted uses described above. Recommendations will also be based upon applicable VAPHS policies

pertaining to conflict of interest and appropriateness to VA's education missions. Determinations will be forwarded to the VHF CEO and will be final in all cases where the policy expressly prohibits acceptance or expenditure of funds in the manner being proposed. In cases where the existing policy does not clearly allow or prohibit an activity, the individual submitting the request may appeal the determination in writing to the VHF Executive Committee within 10 business days from the receipt of the determination. If no appeal is filed within 10 business days, all determinations are final and not subject to appeal. The Chairperson of the VHF Board of Directors may decide to repeal the Education Office action, refer the matter for discussion at the next meeting of the VHF Board of Directors, or may uphold the determination. The decision is communicated to the requestor in writing by the CEO.

VII. CRADA PROCESS

The Department of Veterans Affairs Office of General Counsel (OGC) has determined that the appropriate agreement mechanism for industry-sponsored research is a Cooperative Research and Development Agreement (CRADA). Many sponsors already have established pre-negotiated CRADAs through the VA Central Office to be used at all VA sites without further negotiation. Project-specific information is included in a "Statement of Work" that is attached to the Master CRADA. Study budgets (both payment schedules and a budget of expenses) must be provided with the "Statement of Work" prior to VHF approval of the CRADA. Grants such as those typically originating from nonprofit organizations and federal agencies are not subject to CRADA requirements. The VA CRADA templates are available from the VHF Office and can also be found on the VA ORD Intranet site.

It is important to contact VHF as soon as possible once a decision has been made to apply for a non-VA grant or clinical trial. This will help avoid unnecessary delays. The coordination of the CRADA will be initiated and managed by VHF. CRADAs are signed by the VA, the sponsor and/or CRO, and VHF with an acknowledgment signature by the Principal Investigator. Investigators may not enter into agreements that bind VHF or the VA. The investigator is responsible for the associated submission of the research project to the applicable review committees.

A. CRADA COMPONENTS

- 1. CRADA document showing all changes made by the Collaborator and VHF against the Model agreement. All documents must be in an editable (i.e. unlocked) MS Word format.
- 2. Draft Protocol/Statement of Work, budget and
- 3. A completed, signed, and dated Research Financial Conflict of Interest Statement by the principal investigator. (OGE Form 450 Alternative-VA 11/2013)

VA Office of General Counsel (OGC) Special Team Advising Research (STAR) will review documents upon receipt and notify VHF within 48 hours if the package is complete. Full review time will be completed within 10 business days from receipt by STAR of completed package. It is expected that review of a Simple or Master CRADA will be completed in fewer than 10 business days. During the review, STAR may reach out to program offices such as the Technology Transfer Program, Office of Research and Development, U.S. Trade Representative, and others, for input and guidance. STAR time spent outside of STAR's jurisdiction does not count against review time. Program offices will provide their review within a reasonable time to OGC. STAR will review any subsequent revisions to the document within 7 business days from receipt.

B. CRADA BUDGETS

Most sponsors provide a draft or starting point for budget negotiations. It is the PI's responsibility to carefully consider if the proposed budget is enough to accomplish the protocol requirements and complete all associated research tasks. VHF will take the lead for negotiating the budget and all indirect costs. The PI will be asked to provide supporting details and

justification (use policy as applicable) for specific funding requests.

VAPHS may require reimbursement of the medical care appropriation for clinical services provided solely for research purposes (38 CFR 17.102 (g); M-1, Part 1 Chapter 15 1982; MP-4 Part V Change 194, November 7, 1985). During the budget process the protocol should be reviewed to assess all associated activities that are necessary to conduct the research. Identify the resources needed and what the costs are to conduct the study.

Identify reimbursable expenses (tests, procedures, etc.). Provide the cost and frequency/quantity. This is needed even if the sponsor wants a budget with a lump sum per visit or per patient. VHF encourages open discussion about the feasibility of studies and associated benefits. If a sponsor is not willing to cover VHF's real costs of doing the study, VHF is not obligated to do the study.

STAR does impose legal review fees for CRADAs. Please work with the Grants and Contracts Manager for current fees.

VIII. REPORTING OF ACTIVITIES

• Quarterly Report

For each service, team or project: this is your opportunity to promote the work that you do. Reports should be a page or more in length and aimed at a general public audience, for use on the web site, social media, in publications/ newsletters, or marketing materials. Highlight individuals, the team, research, discoveries, and scientific knowledge contributions. Include awards, recognitions, honors, publications in the report. Include pictures, graphics and web links in the report.

IX. SUMMARY

Please keep this manual where you can refer to it should you have any questions regarding managing your research or education projects. Please contact the VHF Administrative Office for copies of current forms or check the VHF website.

It is impossible for a manual to answer all questions or to anticipate all problems that may arise. VHF will make every effort to address situations or problems not covered in this handbook in a consistent, equitable, and reasonable manner. Further, while VHF intends to enforce the policies and procedures stated in the document; all of this material is subject to change at any time, with or without notice, at the sole discretion of the Foundation and/or its Board of Directors. The right to alter, amend, add/or delete all or any part of this manual is expressly reserved by VHF.