



OPERATIONS MANUAL

Version 10/27/2016

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I. INTRODUCTION

The Veterans Research Foundation of Pittsburgh (VRFP), 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 as a flexible funding mechanism to support research and education at the VA Pittsburgh Healthcare System (VAPHS). VA-affiliated Non-Profit Corporations (“NPCs”) are established by Congress for the receipt and administration of research and education funds. The sole purpose of an NPC housed in a VA facility is to advance the research and education mission of the Department of Veterans Affairs through the support of approved research and educational activities; to facilitate functions related to the conduct of research as described in sections 7303(a) of authorizing title and education and training as described in sections 7302, 7471, 8154 and 1701(6) (B).

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

Mission Statement: The mission of VRFP is to enhance the health and wellbeing 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 guidelines can anticipate every circumstance or question that may arise. As the Foundation continues to grow, the need may arise to change policies described in these guidelines. 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 VRFP

VRFP 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. VRFP is a member of the National Association of Veterans Research and Education Foundations (NAVREF).

The Corporation is audited annually by a professional external auditing firm. VRFP’s fiscal year runs from January 1 through December 31.

III. ACCOUNTS WITH VRFP

A. ESTABLISHING AN ACCOUNT

Funds administered by VRFP may only be designated to support an approved research or education activity if the individual holds a VA appointment. These activities are performed by these individuals in their capacity as VA employees (with or without compensation). If a VA-salaried account holder terminates VA employment, the individual must obtain a Without Compensation (WOC) appointment in order to continue the activity and maintain funds within VRFP.

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

Education activities supported by VRFP must have approval by the VAPHS Education Office

Special circumstances may be considered, such as donations or grants for a specific activity related to research or education.

VRFP will establish an account upon execution of a new agreement or notice of award or when receiving a check from a funding source. 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 VRFP for each funded project, and each project may be supported by only one unique account.

VRFP 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 (i.e., a clinical trial) or produce a deliverable (i.e., a manuscript) with the funds. Expenditures made using a restricted account must be in support of that particular 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 not tied to contracted or awarded obligations. All unrestricted account funds are owned by VRFP and are part of VRFP's general assets. Unrestricted funds are the result of completed/closed research and education projects. 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. Balances in *unrestricted* accounts are routinely transferred into a residual account by VRFP (Investigators will be notified of the transfer). These funds are not owned by the PI. Expenditures made using an unrestricted account must be in compliance with VRFP's guidelines referenced in this document.

D. DEPOSIT OF FUNDS

Funds may be accepted by VRFP 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 Research Foundation of Pittsburgh and mailed directly to our office. Cash deposits will not be accepted. Funds in VRFP accounts are property of the Foundation and are not to be used for the personal benefit of any investigator. All interest earned remains with VRFP. 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 VRFP.

Transfer from General Post Funds. 38 USC Section 4162 allows funds donated to the VA Medical Center's General Post Funds for general research purposes to be transferred to the Foundation. Funds donated to the General Post Funds for a specific research project may be transferred to the Foundation with the consent of the donor and the R&D Committee. The Foundation shall document any such transfer of funds to appropriately account for all funds received.

Transfer from a Nonprofit Funds may be transferred from accounts at other 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.

Donations Any conditions to be imposed on the investigator and/or VRFP 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 VRFP. 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 VAPHS, residual funds and equipment

associated with that investigator may be retained by the VRFP. 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 VAPHS approved research project linked to the account of an investigator who has left VAPHS, the ownership of the account may be changed to a new PI as long as the change in PI is approved by the appropriate VAPHS Research subcommittee (IRB, IACUC or RSEC subcommittees). Residual funds in the accounts of investigators who are leaving VAPHS may not be transferred to other investigators, but will be transferred to a VRFP administrative account as long as there are no contractual requirements to return the funds to the sponsor. 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 Executive Director(ED). Such reassignments of equipment may be appealed to the Board.

G. DELINQUENT ACCOUNTS

With the exception of federal sub 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 VRFP with a written plan for reactivating the account. If no such plan is provided or the plan is not approved the account will revert to the general administrative account. Investigators will be notified of the transfer.

I. CLOSED/COMPLETED ACCOUNTS

When all activity of a research or educational project have been accomplished and all deliverables and other contractual obligations have been satisfied the project is completed. As a final action the PI needs to complete and send the Project Closeout Form to the VRFP Administrative office.

J. ACCOUNT REPORTS

Summaries of all transactions (deposits and expenditures) for each 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 RELATED TO RESEARCH & EDUCATIONAL ACTIVITIES

A. GENERAL INFORMATION

Expenditures made through VRFP must be in support of an approved research or educational project. All expenditures must be in compliance with Internal Revenue Service (IRS) guidelines for non-profit corporations, VHA Handbook 1200.17 and Federal accounting standards OMB Circular A-110 and A-122.

The following requirements apply for all purchases made through VRFP:

1. Sufficient funds must be immediately available in the requestors account to cover costs. Some exceptions may apply, as with the example of a federal sub award.
2. A clear justification for the purchase and how it pertains to research or education.
3. All purchases for sponsored research projects must be reasonable and necessary for the performance of the project as well as allowable and allocable under the terms and conditions set forth in the agreement.

There will be a delay in placing the order or providing reimbursement until justification documentation is received.

Written documentation is required for personnel authorized to sign on accounts other than the PI. Using the "Delegation of Authority" form the PI will identify all individuals who have signature authority for requesting disbursements from the account.

A properly completed "*Purchase Order (PO)*" form shall be required for all purchases of goods and services, with the exception of travel authorization and expense reimbursements or direct payment requests, which require the preparation of a separate form described elsewhere in this manual. This completed form should be submitted to the Administrative office for review and approval by the ED. Every effort will be made to achieve delivery as requested in the "Date Required" field. The project account will be charged for any increased shipping costs resulting from rush orders. Any questions or problems with the order, e.g., significant price difference, back orders, discontinued products, will be conveyed to the individual named on the PO prior to placement of the order.

If an order is not received within the expected time frame, the intended recipient should notify the Administrative office, which will follow up regarding anticipated delivery. Upon delivery, packing slips are retained by the office and should be attached to the PO. Payments are made after an invoice is received and matched to the corresponding PO and packing slip. If a packing slip is lost or not provided the purchaser will be required to complete a Packing Slip Replacement form. Some purchases may be made with the credit card if required by the vendor and upon approval by the ED.

The ED is the only official authorized to commit expenditure of funds. The ED will review and approve all expenditures and determine the appropriateness of the request. If an expenditure

request is determined inappropriate within the defined policy, the account holder may request a review and final determination by the full Board of Directors at its next scheduled meeting

B. ALLOWABLE EXPENSES AND RESTRICTIONS

1. **Books/Publications** – Purchase of books and publications with a direct relation to research and/or education
2. **Business Meetings** – Meetings, conferences, workshops, seminars, grand rounds, symposia, and other similar events are accepted components of conducting research and education. 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 VRFP influence whether expenditures related to such events are appropriate for VRFP support. In order to be eligible for VRFP support, a meeting must have a documented research, education or VRFP business purpose. VRFP will not support “entertainment” expenses such as social activities, parties, ceremonial occasions or those that provide amusement. Consequently, in order to be considered for VRFP support by direct payment or reimbursement, VRFP has established the following policy.

Approved Uses:

- a. VRFP business meetings
- a. In association with recruitment of a new clinician-investigator(*Note: Funds cannot be used towards meals and refreshments for VA employees meeting with the recruit*)
- b. Special events, such as award presentations or lectures that include both non- VA and non- VRFP employees.
- c. Infrequent VA staff, committee, or department meetings that further the VA research and education mission.
- d. Prolonged (>2 hours) meetings, meetings that extend beyond or occur outside of the normal tour of duty, or meetings occurring over the lunch hour.

Prohibited Uses:

- a. Refreshments/meals for routine VA staff, committee or department meetings
- b. Refreshments/meals for staff holiday parties, retirement parties, or other celebrations
- c. Entertainment costs

For a research related program:

- A request for VRFP 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, meeting location, presenter(s), roster of attendees and each attendee's organizational affiliation.
- When appropriate, the request should tie the meeting to an approved research project.

For an educational program not related to research:

- The education activity must first be approved by VAPHS Education Office.
- Documentation should include an explicit statement of the purpose and how the program will further the VAPHS's and/or 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.

For other appropriate VRFP 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 VRFP'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.
- Funds cannot be used toward meals or refreshments for VA employees meeting with the recruit.

Requests for VRFP support will be reviewed and approved by the ED. VRFP will either provide direct payment or reimbursement based on submission of original receipts. Non-detailed credit card receipts are not sufficient documentation for reimbursement. VRFP requires that meeting organizers obtain **pre-approval** of VRFP 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 VRFP office staff. Requests must be made at least one week in advance prior to the meeting or event.

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 VRFP's non-profit status or the individual's tax liability. The Foundation will not purchase or lease cellular devices/services, monthly costs for home phone lines, DSL service, and monthly internet service or connection fees.

Home Use

VRFP 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. Digital cameras and accessories will be purchased only if there is a documented project-specific need.

- 5. Conferences** – Requests may be approved to organize a conference in which carries out the educational and research mission of VRFP and/or VAPHS. VRFP may contract with sponsors for support and fund raising to cover cost of the conference. VRFP may contract for services necessary to implement the conference and associated activities. Attendee registration and fee payments may be administrated by VRFP. Educational conferences are allowable; when approved by VRFP Education Sub-Committee.

Expenses for the conference may be funded from a research or education account if appropriate original receipts or invoices are provided, along with an explanation of the relationship of each expense to the conference. Acceptable expenses include honoraria, rental of conference space, refreshments, and travel expenses. Promotional materials, agenda, participant lists and other documentation of content should be submitted to VRFP.

- 6. Hiring of Staff** – Employees may be hired to carry out a project(s) for which funding is available. Hiring employees must be coordinated with VRFP Administration. VRFP will assist with advertising and recruiting for a vacant position if required. VRFP's ED has final approval on the hiring of all employees. VRFP is responsible for all human resource administration such as hiring, payroll and termination.

Process Overview for Hiring New Employees

- Investigator or designee contacts VRFP 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 particular project loses those funds, the position will be terminated. Funds must be available to support at least 90 days' 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 candidates CV or resume if a candidate has already been identified.
- Investigators or hiring managers are not authorized to offer a position or salary to any candidate.
- All selected candidates will have offer letters generated and sent by the ED. 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 subject's 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. At VAPHS, IPAs are most commonly implemented to allocate VRFP or University of Pittsburgh employees to VA funded projects. All employees must submit a time card to appropriately document time being loaned.

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)

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 of time 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.
- 12-month break in service required between assignments of 4 consecutive years
- Federal employees subject to a 6 year cap on IPA assignments for life of Federal career (OPM may waive justifiable cases at VA's written request)

Other rules established by the federal Office of Personnel Management or by VA may apply.

Effective January 2015 VRFP has implemented the following changes.

- 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 is 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 VAPHS and VRFP rules and regulations. IPA's 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 VAPHS 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, VRFP office staff will begin the billing procedures and prepare the invoices for approval and processing through the federal governments 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 may be hired by VRFP in a role that differs from their VA role. Investigators seeking to hire a VA employee must first discuss with the ED and will be required to submit a Justification of Joint Appointment Form. Additionally, the Board of Directors must approve any request for dual employment. All requests will require an ethics opinion from Office of General Counsel. VA employees may not work for VRFP on government time (during the government tour of duty). Any salary or wages earned as a VRFP employee must be for hours worked outside of the VA tour of duty and for duty different from the individual's VA work.

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

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** – VRFP 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 includes 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. VRFP classifies fixed asset purchases of \$1,500 and over as equipment, anything less than that is considered supplies. The classification is based on use and ability to be consumed. VRFP will not purchase equipment unless it is supported by VAPHS. Equipment purchased by VRFP (with funds from a VRFP account) becomes the property of VRFP; therefore, the Foundation retains the right to dispose of the purchased equipment. All equipment owned by the VRFP should be identified with a VRFP 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 within the VAPHS must be approved by the Executive Director. Transfer of equipment outside the VAPHS must be approved by the VRFP Board of Directors.
- 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 and University of Pittsburgh 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 VRFP Administration prior to any work being offered and must be affiliated with an approved project or activity. This request must indicate the specific service to be provided and the fee to be paid.

The IRS has imposed severe penalties when individuals have been paid as independent contractors instead of employees. The IRS considers 20 factors in determining whether an individual should be determined an employee or a consultant - whether sufficient control is present to establish an employer-employee relationship. Meeting just one of the conditions may qualify the worker as an

employee. Not every factor is applicable in every situation and the degree of importance of each factor varies depending on the type of work and individual circumstances. However, all relevant factors are considered in making a determination.

Definitions:

Independent Contractor – An individual or organization that provides services that are generally technical, unique, and infrequent where no Employer-Employee relationship exists. Examples of personal services include: word processing, technical editing, translation and technical reviews or appraisals where there is a deliverable and no right of supervision or control of the service.

Consultant – A consultant is a category of Independent Contractor that provides highly specialized services, validated by curriculum vitae documenting an individual’s professional qualifications.

Employer-Employee Relationship – Such a relationship exists when VRFP has the right, regardless of whether it exercises that right, to supervise and control the manner of work performance as well as the result of the service provided by an individual.

Independent Contractor Relationship – Such a relationship exists when VRFP has the right to control only the result of the service provided and not the manner of performance of the service provided by the entity.

1. 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.
- To assure that an employee’s VA and private interests remain separated and to safeguard against charges of favoritism or ethical violations in the acquisition of goods and services, VA-paid employees may be Consultants only in rare circumstances where the work to be done is clearly distinct from VA duties and is approved by the Board of Directors.

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 VRFP staff during the course of their normal duties.

For services of consultants supported from federal funds:

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 that 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 VRFP's administrative office.
- VRFP 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.

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 VRFP 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 VAPHS grounds (i.e., VAPHS is unable to provide space for the activity).

Clinical Care/Procedural – when itemized or specified in an approved project budget as VA reimbursable items; funds may be used to reimburse VAPHS for over and above standard of care services. All MOU's and/or support letters must be submitted to VRFP.

14. **Licenses / Exams** – In general, VRFP accounts **may not be used** to support 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 individuals who are **not** VA employees (i.e., research coordinators who are VRFP employees) and for whom the certification/licensures directly related to the approved research project. VRFP *prohibits* use of funds in any account to pay for professional licenses

and fees for VA employees.

Tests and exams for college, medical school, law school, etc. or admission **may not be paid.**

15. **Registration** – Payments may be made for registration fees associated with continuing education or professional organization activities as long as the attendance is for a purpose directly related to a VRFP research or educational project and has been approved by the VAPHS Education Office. Registration payments may be made for non-degree courses run by professional organizations that are directly related to the research or education activities of the investigator or research staff. Payment requests to VRFP require submission of supporting documentation. The documentation must include the original registration statement and a written description of the relationship of the course to the approved research project.

For future research or education conferences/seminars, VRFP prefers to approve pay for registration fees before the event is held.

16. **Recruitment** – Reimbursement may be requested for expenses incurred by a VRFP applicant and spouse for an interview trip, if the applicant is being recruited for a position that will enhance the mission of VRFP. Reimbursement for the applicants 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, meals, 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. VRFP support letters must be submitted to VRFP 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 payments are taxable income. All subjects will be required to complete a W9 form. VRFP is required to report payments made for time and effort totaling \$600 or more in a calendar year and will issue IRS form 1099 to qualifying payees. VRFP 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 VRFP administered projects must utilize the ClinCard system; however there are circumstances in which check payments may be authorized (i.e. one time payments, studies in which the subjects are never seen at the site etc.). Use of check payments requires prior approval by the ED. Requests for a check payment must be made to the VRFP office by completing the “*Participant Check Payment Request*” form. PI’s may approve each request or assign a designee as

approver of payment requests.

18. **Payment to Speakers** – Payment to a speaker is considered to be an honorarium and will be reported to the IRS as income. A complete W-9 form must be obtained prior to payment.
19. **Personal items** – Personal services **will not be paid** through VRFP. 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, chauffeur). 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 VAPHS address. Organizational memberships cannot be paid using VRFP 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 particular 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 VAPHS or VRFP is required to join the organization to serve as the official representative of VRFP to that organization.
21. **Supplies** – May be purchased with reasonable rationale provided. Lab animal orders require approval by the animal lab supervisor in advance to ensure project has been approved and that space is available.
22. **Travel** – VRFP funds may be used to support travel expenses associated with furthering or facilitating appropriate research or education activities unless they are 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 two weeks prior to intended departure in order to allow sufficient time for approval.

Guidelines and Requirements for VRFP support of travel

- Acceptable Travel – 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 of 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 – VRFP 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 institutional affiliation. Failure to give primary identification to VA can be harmful to the agency and future funding opportunities. The travelers VA affiliation should be identified appropriately in conference brochures, name tags, attendee rosters, etc.

- Approval Authority – Approval of travel related expenses resides with VRFP Administration. Exceptions to stated policy may be made only by the Executive Director or the Board of Directors. A fully completed “*VRFP Travel Authorization Request*” form must be submitted to the VRFP office staff at least two weeks prior to departure. The travel request should be completed with everything you want 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 VRFP 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 VRFP supported travel. Following approval, the traveler will be notified so that they may begin to make arrangements.

VAPHS imposes special requirements for foreign travel for VA-paid employees.

VA-paid employees are responsible for complying with these requirements.

- Travel Status – 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 Chairman of the Board.
- Advances- No cash advances or reimbursement 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 ED.
- Transportation – 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, taxi cabs 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 cab fares requested will require a separate justification attached to the traveler's reimbursement request. These taxi exceptions will be reviewed and approved by the Executive Director 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 Executive Director.

- Rental Cars – Rental cars may be used only when such rental is justified as being more advantageous to VRFP 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. Rental cars use must be pre-approved by the Executive Director. It is the traveler's/requestor's responsibility to provide a cost comparison and justification as part of the request.
- Air Travel – Economy class shall be used. The exception for use of upgraded service for medical necessity requires approval of the Executive Director 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.
- Baggage – Baggage includes both the traveler's personal property and any VA or VRFP property. VRFP will reimburse for one checked bag. Excess baggage charges may be allowed if justified by an explanation of the circumstances and provision of a legible receipt for such charges.
- Stopovers and Deviation- 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.
- Use of Private Automobile – Use of private automobiles must be approved in advance by the Executive Director. 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 return flight. Reimbursement will be made for reasonable laundry and dry cleaning costs

if the hotel stay is five nights or more. In the case that there is no predetermined hotel sites then travelers will be reimbursed according to the federal per diem rates for destination cities.

- 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.
- Cancellations- 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.
- Foreign Travel- 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.
- Spouse/Partner Travel-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.
- Local Travel- VRFPP 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 travelers home and workshop which is less than or equal to the distance between the travelers

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. VRFP 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 Executive Director 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) day time 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 VRFP 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 VRFP office staff using the “VRFP 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 amount VRFP and VAPHS or the University of Pittsburgh, a copy of the VAPHS and/or the University travel report must be included.

Requests for reimbursement of other business-related expenditures must be submitted to VRFP 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).

All requests for reimbursements will be reviewed by the Executive Director, and if deemed necessary, by the Board of Directors. 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 Executive Director 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 VRFP office. All invoices and shipping documents are to accompany the shipment.

VRFP has established accounts with certain vendors. Use of these accounts can eliminate duplicate paper work and in most cases, it will reduce the amount of time for the delivery of the needed product. Please contact the VRFP Administrative Office for more information.

Reimbursements will not be allowed for expenditures made prior to the time that funds were deposited in the account. Receipts are required for all reimbursements. VRFP does not make payments to credit card companies. VRFP 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 year end financial close of the books. Expense request after December 15 may be booked in the new fiscal year.

D. HOW TO INITIATE A Contractual Services Agreement(CSA)

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 actually 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 VRFP 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.

- VRFP will draft a contract and work with the contractor to have it executed.
- VRFP will scan the contract into its shared file of CSA's 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.

Investigators may also submit a Contractual Services Agreement for review, ten working days prior to commencement of the contract.

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

V. **INDIRECT COSTS and OTHER ASSESSMENTS**

Indirect costs represent the expenses of doing business that are not readily identified with a particular grant, contract, project function or activity, but are necessary for the general operation of the Foundation and the conduct of activities VRFP performs. Investigators should incorporate indirect costs assessments when developing project budgets and communicate this requirement to funding sources.

VRFP does not yet have a federally negotiated rate and as such we are currently subject to the 10% de minimis rate. Please contact VRFP's administrative office when you begin to prepare your federal applications to confirm we do not have a federal rate. VRFP's Board of Directors has imposed the following rate's for the type of projects specified below:

Clinical Trials- 25% to 35%

Educational Activities- 23%

Unrestricted Donations/Public Contributions-10%

Rate adjustment requests must be accompanied by a justification from the Investigator and supporting documentation from the organization of their maximum allowable rate. In special circumstances indirect costs may be waived on funds from other non-profit organizations that have a stated policy which prohibits indirect costs. The investigator is responsible for providing this documentation which will be submitted to the Executive Committee for approval.

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. 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.

VI. INVESTIGATOR ACCEPTANCE OF HONORARIA OR SPEAKER FEES

VRFP will not accept honoraria provided to an investigator as payment (such as of speaking fees, writing fees and consulting fees) for participation in an activity as these potentially pose ethical problems, may impose an unexpected tax liability on the donor, and require VRFP 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 VRFP, that person should accept the payment personally, pay the applicable taxes and then make a personal charitable donation to VRFP. If you have questions, Please reference the Payment of Honoraria Decision Tree

VII. EXTERNAL FUNDING

External funding primarily comes from two sources: commercial companies and granting agencies (Federal and Private). Either source may initiate contact with VRFP 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. CDA's must be submitted to OGC for review unless a master CDA has already been approved by the VA STAR team. If approved, the CDA can be signed by the ACOS R&D. If the PI is interested in the potential research project, the PI should contact the ED to discuss the CRADA and budget review process. Budget negotiations will be handled through VRFP Administrative Office. 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. PI INITIATED CONTACT

PI initiated external funding by commercial companies begins with the PI identifying a sponsor who may be interested in funding the proposed research project. Some pharmaceutical companies have categories of research projects for which they have an open submission process or proposals may be submitted cold. These types of PI initiated proposals usually involve discussions between the PI and pharmaceutical representative prior to submission so that there is a reasonable expectation that the proposal will receive serious consideration. When the decision has been made to prepare a proposal for submission, the PI should contact the ED to discuss the

contracting process.

PI initiated external funding by submitting a proposal in response to an RFP to a State, Federal, or Private funding agency is highly encouraged. These include funding by the Department of Defense (DOD), National Institute of Health (NIH), National Science Foundation (NSF), Health and Human Services (HHS) for which opportunities can be found at Grants.gov. Private and other non-profit organizations including the American Heart Association, Multiple Sclerosis Society, etc. can be found on their internet sites. As soon as a decision has been made to submit/respond to a RFP or funding opportunity a notification to the ED should be submitted. As the proposal preparation identifies additional partners, sub-awardees, physical facilities (space and services) needs a detailed email should be submitted to the ED with the revisions. VRFP will make key role determinations concerning prime awardee, consortium, and sub-awardees in accordance with all applicable State and Federal laws and regulations as well as, common ethical standards. Funding must be requested and funded in the most direct line possible to the people, facilities, and patients involved in the research. In other words, if the work is done at the VA, by VA/VRFP employees, with VA patients VRFP should be the prime recipient of the award. Principal Investigators cannot sub-award to themselves and a prime or sub-awardee organization cannot be a pass through for funding.

When responding to an RFP or open solicitation the award announcement and program contact are key resources that should be fully utilized during the proposal preparation stage. Everyone contributing to the proposal should read the award announcement and all documents provided to through hyperlinks in the text. If there are any questions as to how the announcement guidelines should be interpreted or how they apply the current proposal situation the PI should ask for a clarification from the designated solicitation contact.

VRFP will make every attempt possible to provide you with assistance for timely submission of funding requests. Please provide a copy to VRFP for review and approval before submitting. Other submissions must be made electronically using an on-line interface and may require account set-up days or weeks prior to submission. VRFP maintains accounts with many of the common systems: Grants.gov, EBRAP, ERAcommons, etc. Please discuss the application submission process and requirement with VRFP in the early days of proposal prep so that there are no last minute roadblocks preventing submission.

C. FUNDS DONATED FOR EDUCATION AND SCHOLARLY ACTIVITIES

The VRFP may accept and/or administer funds donated to the VRFP 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 VRFP and must be returned to the VRFP upon completion of the educational activity or upon

separation or termination of the employee. All expenditures must follow the pertinent VRFP policy.

1. Permitted Uses

VRFP 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 VRFP.
- Appropriate employee education and training activities consistent with the mission of the VRFP.
- Patient education and training activities consistent with the mission of the VRFP.

2. Prohibited Uses

VRFP may not support the following activities:

- Any expenditure that is contradictory to any other existing VRFP 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 VRFP 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. improve 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 VRFP support of education and/or activities must be submitted to the VRFP 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 VAPHS Education Office 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 VRFP Executive Director 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 determination in writing to the VRFP Board of Directors 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 VRFP Board of Directors may make a determination to repeal the Education Office action, refer the matter for discussion at the next meeting of the VRFP Board of Directors or may uphold the determination. The decision is communicated to the requestor in writing by the Chairperson of the Board of Directors.

VIII. 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 VRFP 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 VRFP Office and can also be found on the VA ORD Intranet site..

It is important to contact VRFP 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 by VRFP when the PI provides the necessary information regarding the project and sponsor contacts. CRADAs are signed by the VA, the sponsor and/or CRO and VRFP with an acknowledgment signature of the Principal Investigator. Investigators may not enter into agreements that bind VRFP or the VA. The investigator is responsible for the associated submission of the research project to the IRB/ R&D Committee.

A. CRADA COMPONENTS

1) CRADA document showing all changes made by the Collaborator and VRFP against the Model agreement. All documents must be in an editable (i.e. unlocked) MS Word

format.

- 2) A completed STAR New Project Cover Sheet
- 3) Draft Protocol/Statement of Work, and
- 4) A completed, signed, and dated Research Financial Conflict of Interest Statement (OGE Form 450 Alternative-VA 11/2013)

STAR will review documents upon receipt and notify VRFP within 48 hours if the package is complete. Full review time will be completed within 10 Federal business days from receipt by STAR of completed package. It is expected that review of a Simple or Master CRADA will be completed in less than 10 Federal 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. VRFP does not have the medical expertise or experience to review acceptability of funding to accomplish the medical research. It is the PI's responsibility to carefully consider if the proposed budget is sufficient to accomplish the protocol requirements and complete all associated research tasks. VRFP 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 requires 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 you should review the protocol to assess all the 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. VRFP encourages open discussion about the feasibility of studies and associated benefits. If a sponsor is not willing to cover our real costs of doing the study, do not feel as if we are obligated to do the study.

STAR does impose legal review fees of CRADA's. Please contact VRFP Admin for these fees.

IX. REPORTING OF ACTIVITIES

1) Monthly Project Reports

We ask that a status update for each project be provided no later than the 10th of the following month. Reports should include items to be invoiced including a statement of patient enrollments, study visits, IRB submissions and any other milestone payments that may be owed according to the agreement. The information provided for invoicing will be used to estimate the funds earned (accruals) and will be incorporated into the quarterly investigator statements as accrued revenues.

2) 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.

3) Provide information for VRFP's web site.

We need a picture of each team member, title, degrees, and area(s) of research. You may also include list of publications, research activity description, and links (Facebook, on-line publications, professional societies, etc.). Include: pictures, graphics, and images in your submission. These can be anything that can be used as a page background or image of "science" for use without a caption or explanation. In addition we need you to submit specific pictures, graphics, and images to highlight your research with a caption or explanatory text. We would like to expand VRFPittsburgh.org and keep the information current.

X. SUMMARY

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

It is impossible for a manual to answer all questions or to anticipate all problems that may arise. VRFP will make every effort to address situations or problems not covered in this handbook in a consistent, equitable, and reasonable manner. Further, while VRFP 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 VRFP