PAVIR PI Eligibility and Transfer of Funds or Equipment

I. PURPOSE

To define eligibility for PAVIR Principal Investigator (PI) status and transfer of funds or equipment. Principal Investigator, throughout all PAVIR policies, is defined as the responsible official for management of funds in any approved account associated with VA approved research and education activities.

It is the policy of PAVIR to administer funds provided to support VA research or education activities within the guidelines approved by the Board of Directors and in accordance with applicable regulatory requirements. All PAVIR administered research studies must maintain full VAPAHCS Research & Development Committee approval(s).

II. PRINCIPAL INVESTIGATOR STATUS

Below is an outline of the processes which apply to most cases. However, circumstances may differ in specific situations. Researchers with questions regarding their PI eligibility may wish to contact VAPAHCS Research Administration or PAVIR as soon as practical.

In all cases, there will be no dual compensation for work performed.

A. New PIs, or PIs new to the VAPAHCS research community

   PAVIR strongly encourages all investigators who are new to PAVIR and VAPAHCS sponsored project administration to schedule a visit with PAVIR staff to learn more about how PAVIR supports VA research and education.

B. For VA-paid academicians with MCL or UTL Stanford faculty appointment

   Automatic eligibility

C. For researchers without an MCL or UTL Stanford faculty appointment

   1. Researchers who wish to submit an application or to conduct a project serving as the PI must request and maintain VA PI eligibility status from VAPAHCS Research Administration. VAPAHCS PI status must be obtained prior to submission of a proposed project through PAVIR.

   2. Researchers who have previously conducted research in their own name are most likely VA or PAVIR paid at the time of project submission. Researchers who are not VA or PAVIR paid at the time of project submission must become VA or PAVIR paid employees as soon as practical once a proposed study is funded.

   3. Researchers who are neither VA nor PAVIR paid, and for whom there is no documented VA or PAVIR commitment to support them in their role as a PI of VA approved research, cannot serve as a PI on PAVIR administered projects and must identify a PI-eligible researcher for their project.

Exceptions:

For the conduct of industry sponsored, protocol driven clinical trials PI exceptions may be made, but need to be requested prior to engaging into trial negotiations. In any case, VA PI eligibility must be requested and maintained.

III. TERMINATION OF PRINCIPAL INVESTIGATOR STATUS AND DISTRIBUTION OF RELATED FUNDS AND EQUIPMENT

Principal Investigator status will terminate when the PI no longer has an appointment at VAPAHCS or requests termination of PI status. Guidelines for distribution of remaining funds, both from active awards and residual/donation accounts, and related equipment are described below:

A. Transfer of active sponsored awards to another academic or nonprofit institution

   If the Principal Investigator is transferring to another academic institution or nonprofit institution and will continue an ongoing research or education activity, funds from active sponsored awards may, at the discretion of the Board of Directors and with the agreement of the sponsor and receiving entity, be transferred to such institution. Further, equipment that was acquired primarily for use by the departing investigator **may** be considered for transfer.

   In these cases the Principal Investigator should submit a written request to the Chief Executive Officer, delineating the transfer.

For federally funded studies, if the sponsor is amenable to the transfer, then PAVIR will relinquish the grant and any equipment purchased with grant funds which is still needed for the grant project. Such equipment will be transferred to the new grantee organization, which would assume title.

B. Transfer of donated and/or residual funds

If the Principal Investigator is transferring to another VA and will continue an ongoing research or education activity, residual/donation funds may, at the discretion of the Board of Directors, be transferred to a VA-affiliated NPC. Further, equipment that was acquired primarily for use by the departing investigator may be considered for transfer. In reviewing such requests, the Board will consider sponsor and donor-imposed restrictions on residual funds, whether the transfer will support VA research, and PAVIR/VAPAHCS needs.

In these cases the Principal Investigator should submit a request to the Board of Directors, through the Chief Executive Officer, delineating what is requested for transfer.

No residual funds will be transferred to other than a VA-affiliated NPC. Because PAVIR exists to facilitate VA research and because the funds administered by PAVIR become PAVIR funds, residual funds must be used in support of VA research and education. Therefore, transfer to other than a VA or VA-affiliated NPC would not be in furtherance of VA research or education. The ability of the PI to exercise control over residual funds is solely at the discretion of the Board of Directors.

C. Cessation of research activities or retirement

When a Principal Investigator ceases engaging in research or departs VAPAHCS, residual funds and equipment will revert to PAVIR administration for redistribution.

D. Transfer to a for-profit entity

No funds or equipment will be transferred to such an entity.

I am a Stanford appointed faculty with Stanford PI privileges and VAPAHCS PI eligibility. Can I conduct my Stanford administered industry sponsored clinical trial at the VA as well?

Options:

1. If you have a paid VA or PAVIR paid position, contact CRADAs@PAVIR.org to initiate the negotiation of a VA-based clinical trial agreement to cover your VA based research with the sponsor.
2. If you don't have a VA or PAVIR paid position, nor is there any commitment from the VA or PAVIR to offer you a paid position, you must identify a VA based colleague who can serve as the VA Responsible Investigator (VARI) of a VA based project. Then, contact CRADAs@PAVIR.org to initiate the negotiation of a VA-based clinical trial agreement in the name of your colleague. You can serve as the Co-PI on the project.
3. If you have a fee for service arrangement with the VA for clinical work, and if the industry sponsored trial is directly related to your fee for service VA work, request an exception from CRADAs@PAVIR.org. PAVIR will coordinate such an exception with the VA Research Service.
4. If you have a fee for service arrangement with the VA for clinical work, but the industry sponsored trial is not directly related to your fee for service VA work, nor is there a commitment from the VA to extend your fee for service pay to the services integral to the proposed clinical study, you cannot serve as the PI on a VA based study. To conduct the work, you must identify a VA based colleague who can serve as the VA Responsible Investigator (VARI) of a VA based project. Then, contact CRADAs@PAVIR.org to initiate the negotiation of a VA-based clinical trial agreement in the name of your colleague. You can serve as the Co-PI on the project.
5. If you only want to recruit patients from the VA, but don't want to engage in research at the VA, you can collaborate with your colleagues at the VA to find interested patients. You cannot post recruitment materials, nor can you enroll patients (conduct informed consents) at the VA. Interested patients have to go to your performance site at Stanford.

If the study will be performed at the VA:

- Based on institutional differences regarding compliance and liability, there must a fully executed Clinical Research and Development Agreement (CRADA) to conduct VA-based work with your industry sponsor.
- The IRB protocol must be amended to add the VA as an additional site and the VARI. You also have to add a second

informed consent form for VA use. The Stanford IRB protocol can stay in the primary PI's name, as long as the VARI is added as a Co-PI.
- The study must be submitted to the VA R&D for review and approval prior to commencement of the work at the VA.

I am currently a SU appointed faculty without Stanford PI privileges and would like to conduct a sponsored study in my own name at the VA, administered by PAVIR.

Options:

1. You must be a VA or PAVIR paid employee, and you must request and maintain VA PI eligibility with the VA Research Service. In the absence of VA or PAVIR employment, you must identify a VA based colleague who can serve as the VA Responsible Investigator (VARI) of the study.
2. If you are not a VA or PAVIR paid employee, but if PAVIR can substantiate that you are being actively considered for a VA or PAVIR paid position, you may be eligible to submit a proposal and conduct a VA based study through PAVIR. You will also need to request and maintain VA PI eligibility through the VA Research Service.

Question: If have no Stanford academic appointment, nor am I Stanford staff. My sole employment is with VA and/or PAVIR. Can I submit an application for a VA based study through PAVIR?

As long as you request and maintain VA PI eligibility, yes.
