Guidelines for Sponsored Research Administration between PAVIR and Stanford University

The Palo Alto Veterans Institute for Research (PAVIR) and Stanford University (Stanford) are committed to complying with the agreement they executed in September 2006, hereafter referred to as the Master Agreement. The Master Agreement is the governing document for administering sponsored research and education activities conducted by VA investigators, i.e., individuals who hold a coterminous Stanford faculty and VA appointment – Dually Appointed Persons (DAPs), and other VA investigators. DAPs do not include the titles or appointment lines of Clinical Educators (CEs; "Clinical" Professors of any rank), Instructors, or "Affiliated" or "Adjunct" Professors of any rank. Rank consists of Assistant Professor, Associate Professor, or Professor. The VA Palo Alto Health Care System (VAPAHCS), PAVIR, and Stanford are affiliated and collaborate to advance the quality of medical care and research for Veterans.

The Master Agreement identifies PAVIR as the appropriate institution to propose and manage sponsored research when more than 50% of Modified Total Direct Costs (MTDC), including the value of contributed effort of VA personnel working on the project, will be expended in VAPAHCS space. In the analysis of preponderance of work, PAVIR and the School of Medicine's Research Management Group (RMG) will also evaluate the use of VA resources (e.g., equipment, personnel, patients, patient specimens, or patient information); these inform the consideration of what is VA Research.

PAVIR and the Stanford Research Management Group (RMG) manage all research for DAPs and other VA principal investigators other than funding from the VA. PAVIR and RMG have collaborated to ensure that during proposal development they can validate whether proposals and awards should be managed by PAVIR or RMG. The process involves collecting information that will be used to determine whether the preponderance of work will take place at the VA or Stanford.

For all Research at VAPAHCS, regardless of funding source, the VAPAHCS Research Administration Office, under the Associate Chief of Staff for Research (ACOS-Research), manages all VA research regulatory oversight, research administration of the Research and Development Committee (R&D Committee) and its process, facility research space and other resources, and VA research strategic and scientific planning at VAPAHCS, in collaboration with Stanford School of Medicine leadership. The VAPAHCS Research Administration Office brings forth research projects to the VAPAHCS R&D Committee for review and final approval. The R&D Committee has an established process for reviewing proposals and making the necessary determinations. This process takes place while the proposal is being considered and decided by the funding agency and can accommodate the need for expedited review.

To ensure compliance with the Master Agreement, PAVIR and Stanford rely on the following:

A. **VA Research** is defined in VA Directive 1200.01 as "research conducted by VA investigators (serving on compensated, WOC[1], or IPA[2] appointments) **while on VA time or on VA property.**" VA research may be sponsored or non-sponsored. Effort used on non-sponsored VA research counts against total available VA hours for research. All intended VA research projects must be submitted online to the VAPAHCS' research projects and personnel information system ("RDIS") which is managed primarily by VAPAHCS Research Administration Office, in conjunction with PAVIR. Such projects must then be reviewed and approved by VAPAHCS's Research and Development Committee (R&D Committee). R&D Committee approval of research at VAPAHCS involves a comprehensive review by R&D Committee subcommittees of each submitted research project, including scientific merit, relevance to VA and Veterans, feasibility, safety, human subjects protection, animal use and care, potential conflict of interest, pharmacy, and other clinical impact, among others. Privacy protection, information security, and other contractual agreements are reviewed at the VAPA or VA regional/D.C. level, when needed for a specific project.
B. **PAVIR,** per the authorizing legislation codified at section 7361-66 of title 38, USC, is only allowed to administer research fitting the description of VA Research as well as VA-approved education activities.
C. VA employees must inform PAVIR of every planned proposal submission to a sponsor other than VA involving any VA paid person. Stanford and PAVIR will conduct an analysis of the individual's involvement to determine the scope and preponderance of work, in consultation with the VAPAHCS Research Administration Office/ACOS-Research. This analysis will determine whether PAVIR or RMG should submit the proposal and will inform whether a subaward to either Stanford or PAVIR is needed.
D. **Available effort for VA research** will be defined as an upper-limit percentage of available VA hours according to a DAPs' Stanford Faculty line as follows:
    - UTL = 85%
    - MCL = 75%
    - Research = 95%
    - Teaching = 10%
E. The **Institutional MOU** identifies all DAP investigators who hold coterminous faculty appointments at VAPAHCS and Stanford. The Institutional MOU is updated annually. As required by NIH regulations, the Institutional MOU specifies each DAP's appointment title, distribution of compensation, responsibilities of the investigator, and the upper limit of available research hours at each institution. Stanford will engage the VAPAHCS Chief of Staff and ACOS-Research early during the DAP candidate's interviewing process to collaborate on the drafting of VA responsibilities and offered

resources in the offer letter. In no case will an offer be extended to a DAP without input from VAPAHCS.

F. The **Individual MOU** outlines how the coterminous VAPAHCS/Stanford appointment of each DAP constitutes 100 percent of his or her total professional effort; Stanford appointments are based on an average 60-hour work week, while the VA's full-time work week constitutes 40 hours. Each DAP will have an Individual MOU executed between PAVIR and Stanford specifying the effort allocation. In no event will any DAP receive compensation for more than 100% professional effort.

G. PAVIR and Stanford recognize that once it is determined whether Stanford or PAVIR will manage the proposal and award, it will often be the case that the project will require a subaward to the other party. The subaward will ensure that project activity such as PI and staff effort, animal care, data use and security, and core facilities are managed appropriately and effectively and as required by the Master Agreement. The subaward may also require personnel agreements, e.g., JPA, rJPA, PSA, to ensure proper funds flow.

Frequently Asked Questions:

1. **What is the determining factor for which institution administers a VA employee's sponsored research?** Where the work on the specific project is performed. If the preponderance of the research takes place in Stanford facilities, Stanford will administer the award. If the preponderance of the research takes place on VA grounds or on VA time, PAVIR will administer the award. When discrete activities identifiable in a separate scope of work exist at the other institution, a subaward will be issued for that work. In the uncommon scenarios in which PI-specific circumstances do not conform to the above, PAVIR and Stanford RMG, in conjunction with the VAPAHCS Research Administration Office/ACOS-Research, will confer and discuss with the PI.

2. **When is it appropriate to use DAP VA effort or other VA resources on Stanford-administered projects?** It is appropriate when the DAP contributes, specifically in their VA capacity, a scope of work within the Stanford-administered project. This specified scope of work in their VA capacity requires review and approval by VAPAHCS R&D Committee prior to initiating the work. This VAPA research is then subject to VA research policies and regulations. It would not be appropriate to apply VA effort to Stanford-administered project(s) when the DAP is not contributing in their VA capacity, because this would mean that VA effort, supported by VA, is being borrowed by or donated to non-VA research activities. The VAPAHCS R&D Committee will consider the importance, relevance, and benefit of the research to the VA mission, and the VA resources that are being utilized in the project, among other aspects. The R&D Committee is responsible for reviewing and approving VA research; it does not approve Stanford projects.

3. **What is contributed VA effort?**
It is VA-paid effort expended to work in the PI's VA capacity in support of VA research with VAPAHCS R&D Committee approval; VA-paid effort may only be charged to a non-VA sponsor for the purpose of reimbursing VA. VA-paid employees do not have any VA effort available for non-VA research. Therefore, contributed VA effort is not "donated."

4. **How can a Research Process Manager (RPM) or other Administrator know when a DAP has maxed out their VA research time?**
The upper limit of available VA research hours is documented on the Institutional MOU. PAVIR and RMG will collaborate in the preparation of individual MOUs for each PI; the individual MOU informs the PI, PAVIR and RMG how available research time is allocated. Using updated Other Support information from the PI's Stanford Department, the individual MOU breaks down the total effort per Institution by hours (percent time) and calendar months. Any effort that is not applied towards sponsored research will be applied as Clinical, Teaching, Administrative & Non-Sponsored Research (CTAN) time.

5. **What is considered full-time VA employment?**
An 8/8 or 100% appointment at VA is 40 hours per week.

6. **Under what circumstances is it OK for a DAP to have all their funding administered at Stanford?**
Only under very unusual circumstances when the necessary resources are not available at VAPAHCS or there are other special conditions. Criteria for this are evaluated on a case-by-case basis by the VAPA ACOS-Research and the R&D Committee. The process begins with Stanford informing PAVIR and the VAPAHCS ACOS-Research of each case.

7. **Why is the sponsored research for some DAPs administered by PAVIR when work is performed in Stanford space?**

There are cases when a DAP occupies Stanford space because VA space is not available at the time of the DAP's (or project's) start date. The intent is for the DAP to be conducting VA Research in VA space upon arrival; however, when not possible and Stanford space is used, PAVIR will still submit proposals for these DAPs as normal. This is to reduce undue delays to research and/or administrative burden of subsequent grant transfers. When Stanford space or resources are needed and not detrimental to the completion of the research, a subaward to Stanford may be appropriate.

[1] Without Compensation
[2] Intergovernmental Personnel Act