Palo Alto Veterans Institute for Research

Driving Veterans Health Innovation

PI Orientation

PAVIR / VA Palo Alto Health Care System [VAPAHCS]

Presenters:

PAVIR Contracts & Grants

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Section 1

PI ELIGIBILITY; RESEARCH AND EDUCATION DEFINITIONS

PI Eligibility

- MCL / UTL Stanford Faculty appointment = automatic

- No MCL / UTL SU Faculty Appointment:
  - Request and maintain VA PI eligibility from VAPAHCS Research Service
  - Must be VA or PAVIR paid at the time of proposal submission <u>and</u> throughout the performance of the study.
  - If not VA or PAVIR paid, must identify a PI-eligible researcher; can be listed as Co-I.
    - If funded, it is possible to have role officially changed to PI, but must coincide with a VA PI appointment through VA Research Administration.
    - Newly assigned PI must become PAVIR or VA paid employee.

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PI Eligibility

- To request PI eligibility send an email with:
  - CV or NIH Biosketch
  - Grant Mechanism to which you want to submit
  - SOW or abstract

…to the following:

- Kristin.Frazier@va.gov – Kristin Frazier, AO for Research Administration

- ptsao@Stanford.edu – Phil Tsao, PhD, ACOS for Research

- Cc: Your mentor, if applicable. ACOS is likely to seek the input of your mentor as your PI eligibility request is considered.

- Cc: KLynam@pavir.org – Kerstin Lynam, CEO

- CC: Estaats@pavir.org – Elaine Staats, Director of Sponsored Research

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VA Definition of Research

- Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. [...] Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research.

-VHA Handbook 1058.05 §4d

-VHA Handbook 1200.05 §aa

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Definition of VA Research

- VA research is research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.

-VHA Handbook 1200.01 §3b

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Definition of Educational Activities

- Educational activities are activities necessary to support VHA's medical education mission, including training health care and other professionals.
  - may constitute research if the activities are designed to expand the knowledge base of a scientific discipline or other scholarly field.
  - such activities do not constitute research if they are designed and implemented for internal VA purposes, or are not designed to expand the knowledge base of a scientific discipline (or other scholarly field).

    -VHA Handbook 1058.05 §4f

- NPCs may facilitate the conduct of education and training activities as approved by the Education Committee regardless of the source of funding, the entity administering the funds, or the research or education site.
  - Patient-related activities include education activities for Veterans, their families and guardians that provide instruction or other learning experiences related to improving or maintaining the health of Veterans.

    -VHA Handbook 1200.17 §2

- Education activities usually carry a 30% IDC burden
  - (e.g. a $10,000 education grant: $7,000 to carry out the purpose of the grant, $3,000 to be allocated to indirect cost)

Section 2

PAVIR, AND VA RESEARCH AT THE VA PALO ALTO HEALTH CARE SYSTEM

About PAVIR

- In 1988 Congress passed Public Law 100-322 (now codified at section 7361-66 of title 38, United States Code) that allowed Department of Veterans Affairs (VA) medical centers to establish nonprofit research corporations (NPCs), forming a unique public/private partnership that dramatically broadened VA's ability to benefit from private and non-VA public support for research conducted at VA medical centers.

- The Palo Alto Veterans Institute for Research (PAVIR) is one of 83 active NPCs that exist due to Title 38 legislation. The advent of these NPCs has been highly productive: in total, the VA affiliated NPCs reported $263Mil in revenues for Fiscal Year 2012. For the same reporting period, PAVIR reported $25Mil in revenues, making it the third largest VA affiliated NPC.

- PAVIR was incorporated in the State of California on November 30, 1988 and is an independent 501(c)(3) tax exempt corporation.

About PAVIR, continued

- PAVIR's focus is on Driving Veterans Health Innovation, which we address by supporting research and education activities conducted at the VA Palo Alto Health Care System (VAPAHCS). **We are here to serve you.**

- PAVIR administers 182 active research projects, including 65 Federal Prime awards, and 33 subagreements as of February 2015.

- PAVIR has 252 employees, including about 20 employees in its core office, located on the 2nd floor of VAPAHCS Building 101, near VAPAHCS Research Administration.

- To learn more about PAVIR visit our externally oriented website http://pavir.org, or for more internally oriented information, including policies and forms, www.pavir.net.

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PAVIR's Role – Driving Veterans Health Innovation

- PAVIR's mission is to facilitate extramural research and education activities conducted at the VAPAHCS. Areas of support include:
  - **Contracts & Grants**: Comprehensive grants management support including proposal submission, account management, reporting, and financial analysis.
  - **HR**: Recruitment and staffing, compensation, performance management and annual performance review, payroll and benefits.
  - **Purchasing**: Online ordering system including PunchOut capabilities with Bio-Rad, Dell, Fisher Scientific, Life Technologies, Office Depot, Sigma-Aldrich and VWR.
  - **Accounting**: Processes check requests, reimbursements and payments to vendors as well as deposits from sponsors and all general ledger activities.

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PAVIR and VA Similarities

- All research conducted at VAPAHCS requires approval by the Research & Development Committee and must abide by policies and guidelines as published in VA Handbooks.

- PAVIR and VA Research Administration work together to support the breadth of an investigator's research portfolio.

PAVIR vs. VA Research Administration

- PAVIR provides services to VA-based PIs in support of all **extramural** research (i.e. NIH, DoD, Foundation, Industry Sponsored, donations, etc.)

- VA Research Admin supports **intramural** research (i.e. Merit Review Awards, Center funding, CSP, and QUERI, etc.)

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Funding Opportunities through PAVIR

- PAVIR directs communications regarding funding opportunities to the PI Community as applicable without overlapping what Stanford PIs already receive from Stanford.

- Subscribe to listservs, such as
  - NIH http://grants.nih.gov/grants/guide/rss_info.htm
  - DoD http://ebrap.org
  - CIRM https://www.cirm.ca.gov/about-cirm/e-newsletters
  - PCORI http://www.pcori.org/funding/opportunities
  - AHA http://myamericanheart.org/fundingopportunities

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VA Funding Sources

- http://www.research.va.gov/funding

- Check the Research and Development Information system (RDIS) at https://www.rdispaloalto.net/Pinsite

- Check in with Research Administration (Kristin Frazier) for additional information

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RDIS – Research & Development Information System

- RDIS, accessible at http://rdispaloalto.net, is the online system utilized to oversee and monitor the life course of research projects including R&D approvals, personnel, and sponsorship activities.
  - Policies
  - Education
  - Compliance assessment, requirements and tracking
  - Forms
  - Many additional helpful resources

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Simplified VA-based Research Project Continuum

| Initial Idea | Basic Ideas, Funding Source/Type, Submission Deadline | Submission | Review |

| JIT / NOA | R&D Approval | Performance |

| Annual Reports Reapprovals | Final Reports | Closeout |

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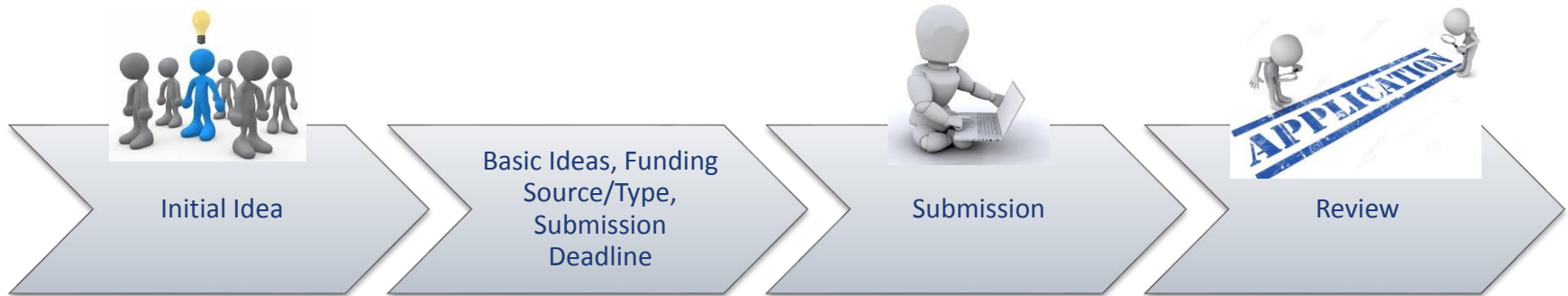
SELECTED COMPLIANCE ISSUES

Conflict of Interest

- Each project conducted at the VAPAHCS requires disclosure of financial conflicts of interest (FCOI) by PI and Co-PIs.

- PAVIR collects disclosures for each PAVIR administered project. If funding is granted by a PHS agency, specific training in FCOI is required and will be initiated at the time of award.

- Positive disclosures of FCOI are reviewed by the combined VAPAHCS/PAVIR FCOI Committee.

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R&D Committee and Subcommittees

- The R&D Committee is responsible for advising and assisting the Director in providing oversight, planning, and execution of the VAPAHCS R&D program maintaining high standards throughout.

- Standards include ensuring the scientific and ethical quality of VAPAHCS research projects, protection of human subjects in research, safety of personnel engaged in research, welfare of laboratory animals, security of VA data, and the security of VA labs.

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R&D Committee and Subcommittees

- The R&D Committee meets on the 3rd Wednesday of each month to review full project applications.

- Prior to review, each project is reviewed by the following subcommittees:
  - Institutional Animal Care and Use Committee (IACUC – for projects with animals)
  - Institutional Review Board (IRB – for projects with humans)
  - Scientific Review Subcommittee
  - Research Safety Subcommittee

- R&D Committee Calendar http://pavir.net/contracts-grants/rd-committee-calendars/

R&D Committee Approvals

- R&D Committee approval is necessary to initiate your research project

- PAVIR will not approve any expenses using PAVIR administered funds prior to
    - R&D approval
    - Receipt of Notice of Award or other applicable research contract

Role of PI vs. Institutional Support Staff

- PAVIR and VA Research Admin are the authorized institutional officials for the sponsored funding they each administer

- Each serves as the institutional communicator through which, in most cases, investigators should communicate with sponsors.
  - Exception: Programmatic topics for discussion with funding agency's program directors and like positions. (PAVIR staff will advise if so requested)

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What's Different about PAVIR?

- PI Administrative Accounts for Indirect Costs
    - It is the policy of PAVIR to provide adequate administrative support, e.g., human resources, administrative, financial and technical (IT equipment, consultation and software) support, to investigators to ensure their ability to conduct sponsored research activities in a manner that assures compliance with regulatory requirements. Accordingly, for awards made with the full federally negotiated rate an administrative account will be established for each investigator's use.
    - Within 15 days of the end of the first quarter of a qualified award, PAVIR will establish an administrative account to provide up to 8% of direct cost expenditures FOR YOUR USE (excluding equipment purchases and subcontract costs), for the support of facility and administrative expenses. These accounts will be funded on a quarterly basis, after the fact, to reflect 8% of the actual adjusted expenditures of the previous quarter.

    For more information, visit http://pavir.net/policies/administrative-accounts-for-indirect-costs/

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What's Different about PAVIR?

- ## Spending on food:
  - Lots of oversight, hot button issue because of VA.
  - Be sure to review business meeting expense policy.
  - http://pavir.net/policies/pavir-support-for-meals-and-refreshments-at-meetings/

- ## IT Purchases:
  - Computers must be done through a requisition; we do not reimburse
  - We must adhere to VA requirements or SU network depending on which network you are on.
  - All laptops have to be encrypted – Ed Lee helps w/ people on LAN

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What's Different about PAVIR?

- CA Labor Law (selected items):
  - Overtime for hourly employees
    - greater than 8 hours in a day, as well as
    - greater than 40 hours in a week
  - Employees must be presented a final check on their last day of work if we know about it at least three days in advance.

- Grant Proposals:
  - PAVIR must submit all grants as the Institutional Official
  - Grants may not be submitted to sponsoring agencies without PAVIR involvement.

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Section 4

STANFORD'S ROLE IN VA-BASED RESEARCH

Stanford's Role in VA-based Research

- Stanford's IRB is the IRB of Record for both VAPAHCS and PAVIR

- PAVIR and VA Research Administration maintain communications with Stanford on an as needed basis to ensure appropriate institutional information disclosure as well as transparency of institutional compliance needs and preferences

- If you hold an academic Stanford appointment, we advise that you seek the counsel of your academic department for anything pertaining to employment or other Stanford compliance and other organizational questions

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DAPs, Effort and VA 8ths

- Dually Appointed Persons (DAP) have Stanford and VA effort to devote to **C**linical, **T**eaching, **A**dministrative, and **N**on-Sponsored Research (CTAN) activities as well as Research

- PAVIR and Stanford entered into an agreement which says that if more than 50% of the proposed direct cost (excluding subagreements and capital expenditures) will be expended in VAPAHCS space, then the proposal will be submitted through PAVIR, and if awarded, administered by PAVIR.

- Only DAPs have access to a 60 hour work week; all other researchers and their staff have access to a 40 hour work week

- Each VA appointment is allotted a number of 8ths, and is determined at the time of appointment

- Effort, including VA 8ths, are subject to change

Effort and 8ths:
Conversion Across VAPAHCS and Stanford

Each dual appointment is based on a 60 hour work week, and the portion of responsibilities per appointment differs depending on the number of assigned 8ths to an individual.

Portion of Total Responsibilities				
VA 8ths	VA Hrs	VA %	SU Hrs	SU %
1/8	5	8.33%	55	91.67%
2/8	10	16.67%	50	83.33%
3/8	15	25.00%	45	75.00%
4/8	20	33.33%	40	66.67%
5/8	25	41.67%	35	58.33%
6/8	30	50.00%	30	50.00%
7/8	35	58.33%	25	41.67%
8/8	40	66.67%	20	33.33%

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Parity Pay and Effort

- Parity pay is the difference between the SU appointed salary and what VA pays

- Depending on the SU academic department and other factors, PIs may use PAVIR grants to cover parity pay using SU effort. This scenario does not increase the DAP's total pay. Every individual situation is different. Check with your specific department for answers regarding your specific circumstances.

- The amount of salary that can be charged to a grant is a function of applicable salary cap and a proportion of SU effort devoted and SU effort available (depending on the type of VA appointment a PI has)

- The NIH Salary cap must be pro-rated when calculating a DAP's salary charged to an NIH grant.

- Unpaid effort is part of total available effort

Parity Pay and PAVIR Grants - Example 1

- Example 1: An 8/8ths PI needs 100% of their parity pay covered using PAVIR administered grants. The appointment type has an effort split that is defined as 33.33% (SU) and 66.67% (VA). In order to have 100% of parity paid through PAVIR, the PI must devote the entire 33.33% on PAVIR studies. See below how PAVIR determines the PAVIR grant contribution to Parity Pay in the context of the NIH cap.

Faculty Name: Faculty Member

PAVIR Account Number: AAA0001AGG
Budget Period: 7/1/14 - 6/30/15

Is the effort on grant Stanford Time only? (yes or no) yes
    (Only salary for Stanford time is charged to the grant. Salary for VA time is not charged to the grant.)
Type of appointment in 8ths 8/8 ths

(a)	Total SU Effort - Based on SU/VA breakdown	33.33%
(b)	Of the total annual salary, how much of that is Stanford's portion?	25,000
(c)	What is the NIH salary cap?	181,500
(d)	NIH Salary cap comparison (c x a)	60,494
(e)	What is the % effort that the PI or other academic staff will devote to grant?	33.33%
(f)	% of salary to be charged to grant (e / a)	100.00%
	Continue calculation with the lowest between b & d	
(g)	If b is lowest, the amount of salary to be charged to grant is (f x b)	25,000
(h)	If d is lowest, the amount of annual salary to be charged to grant is (f x d)	-
(i)	If b = d the amount of salary to be charged to grant is (f x b)	-
	Number of months	12
	The amount of salary to charge to the grant is	25,000

Parity Pay and PAVIR Grants - Example 2

- Example 2: If this same PI only has 20% SU effort to devote, only 60% of this individual's SU parity pay portion will be covered.

		AAA0001AGG 7/1/14 - 6/30/15
Faculty Name:	Faculty Member	
Is the effort on grant Stanford Time only? (yes or no)		yes
(Only salary for Stanford time is charged to the grant. Salary for VA time is not charged to the grant.)		
Type of appointment in 8ths		8/8 ths
(a)	Total SU Effort - Based on SU/VA breakdown.	33.33%
(b)	Of the total annual salary, how much of that is Stanford's portion?	25,000
(c)	What is the NIH salary cap?	181,500
(d)	NIH Salary cap comparison (c x a)	60,494
(e)	What is the % effort that the PI or other academic staff will devote to grant?	20.00%
(f)	% of salary to be charged to grant (e / a)	60.01%
	Continue calculation with the lowest between b & d	
(g)	If b is lowest, the amount of salary to be charged to grant is (f x b)	15,003
(h)	If d is lowest, the amount of annual salary to be charged to grant is (f x d)	-
(i)	If b = d the amount of salary to be charged to grant is (f x b)	-
	Number of months	12
	The amount of salary to charge to the grant is	15,003

HUMAN RESOURCES AND WITHOUT COMPENSATION (WOC) VA APPOINTMENTS

Personnel – Hiring Practices

- Investigators may begin recruiting for research personnel as soon as PAVIR is notified by the sponsor that an award is coming.

- Offers cannot be extended until the notice of award has arrived to PAVIR **and** R&D approval is obtained.

- Pre-award spending may be allowable if there is assurance that funding is on its way and if there is a need to complete preparatory work to facilitate the arrival of funding. Pre-award spending requires PAVIR CEO approval.

Human Resources – Hiring Practices

- PAVIR Contracts and Grants Administrators will work with you to <u>estimate</u> salaries based on duties described in the submission.

- Once an award is received, HR will work with you to create a position description that reflects the work that will be performed on the awarded project.

- The laboratory's specific position description will be matched to a more general, standard PAVIR job description, which is tied to the PAVIR salary structure, which will be used for recruiting.

- After completion of the recruitment process, the actual salaries will be based upon a candidate's relevant professional experience, education and the position's standard pay range.

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Human Resources - WOC Appointments

- Every researcher conducting research at VAPAHCS regardless of employment must be registered with Research Administration.

- Every PAVIR employee must complete the **W**ith**o**ut **C**ompensation (WOC) process.

- This process is initiated and managed by VA Research Administration.

- The WOC process can take 6 weeks or more to complete.

- The new hire must complete all their requirements before their paperwork is routed to VAHR for approval.

- It takes VAHR ~3-4 weeks to review and approve the appointment.

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Human Resources – WOC and Start Dates

- PAVIR HR determines the new hire's start date upon obtaining confirmation of an approved WOC appointment.
  - For potential exceptions, such as PAVIR paid administrators, and other specific information, please seek out the VA Research Administration Service or PAVIR HR.

Badging

- All personnel in secure areas will need a temporary badge while they are waiting for formal approval of their WOC appointment. Daily or weekly badges can be obtained from the VA police department and the researcher will need to sign in daily with VA Research Administration.

Personnel Agreements

- **J**oint **P**ersonnel **A**greement (JPA): use of PAVIR funds to reimburse for SAL + FB of a Stanford employee.
  - Policy: http://pavir.net/policies/guidelines-for-jpa-eligibility/

- **I**ntergovernmental **P**ersonnel **A**ct (IPA): use of VA funds to reimburse for SAL + FB of a Stanford or PAVIR employee.

- **R**everse **J**oint **P**ersonnel Agreement (rJPA): use of Stanford funds to reimburse for SAL + FB of a PAVIR employee.

- **P**ersonal **S**ervices **A**greement (PSA): use of non-sponsored funds to reimburse for SAL + FB of a Stanford employee.

- Decision chart and more info: http://pavir.net/contracts-grants/personnel-agreements/

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Section 6

SUBAGREEMENTS AND CONSULTING AGREEMENTS

Employee or Consultant

- All personnel are considered employees <u>unless</u> they meet the criteria to be classified as a consultant

- Consultants typically have their own place of business, a professional license in the subject matter for which they are providing consultation, and charge a rate for their services.

- Independent Contractors cannot perform services typically performed by an employee.

- Consultants who provide professional services for research are paid via an **Independent Contractor Agreement**. For help to determine if a collaborator qualifies to serve as a consultant, complete a PAVIR Consultant Requisition form as posted in the forms section on pavir.net.

- Serving as a consultant is different from a colleague who may be providing support to a research project at no cost or who may be devoting measurable effort on behalf of their institution and need to be paid via a **Subaward**.

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Consultant or Subagreement

Factors that will strengthen the case of a subagreement vs. an Independent Consulting Agreement:

1. The colleague will be involved in the design of the project in a substantive way

2. The colleague will have the potential to patent newly created intellectual property

3. The colleague will be using resources of his or her institution

4. The colleague will most likely be considered a coauthor in associated publications

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Section 7

FACILITIES AND IT

Facilities - Help or Request Modifications

- Facility needs including emergency or routine maintenance and repair are handled by VAPAHCS Engineering

- Submit a VistA Work Order Request through your Service ADP Coordinator

- Engineering response timeframes:
  - Emergencies: within 24 hours
  - High priority: within 7 days
  - Average priority: within 30 days

- The Maintenance Hot Line (x62468) can be used at any time for emergencies, pest control, elevator problems, loss of lighting, damaged ceiling tiles, VA shuttle system/schedule, VA Motor Pool

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Facilities - Specialized Service Centers and Other Resources

- For access to the VMU facilities, contact Laura Gigliello at Laura.Gigliello@va.gov

- For information and access to shared resources, visit the common equipment section at http://pavir.org/means/resources/

Facilities - IT

- In order to assure compliance with VA IT requirements, PAVIR requires all IT purchases to be obtained through its Purchasing systems, i.e. ReQlogic or paper requisition, as opposed to being reimbursed after the fact.

Contact Information

PAVIR

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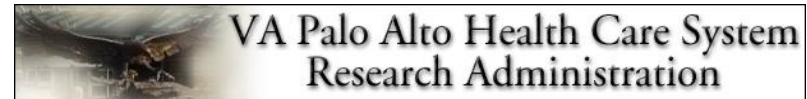
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Commonly Used Acronyms

- VA: http://www.research.va.gov/pride/res/acronyms.cfm

- PAVIR: http://pavir.net/Glossary/