Research VERA and Protected Time

Gery Schulteis, PhD: ACOS R&D, San Diego
VERA dollars are calculated based on expenditures and allocations.

VERA dollars should be used to support indirect costs of running the program at the facility, including the Clinician Scientist Effort to conduct research projects.

Effort spent on research activities should be tracked and mapped to these initiatives.
Research VERA Does NOT Equate to Research Time
Mapping Costs ONLY

• Research VERA = infrastructure support to run a research program, including:
  – Research Protected Time for Clinicians (about 50-55% when we model it)
  – Research Admin/Compliance Support Personnel
  – Proportional Support of Other Admin Services to Permit Research Functions (e.g. Education, Police, HAS, HR, Fiscal, Logistics, Director’s Office, COS Office, etc.)
  – Proportional Cost of Facilities Support Services (Engineering staff, EMS staff, utilities, repairs, maintenance contracts, etc.)
  – Research Leased Space

• About 10 years ago, VA San Diego Research Service developed a model for how/where our Research VERA is spent, in collaboration with our local Fiscal Service
  – The model has been applied about 4-5x in the decade since to assess Research VERA expenses vs. VERA revenue
Where Do I Find Our VERA Data?
Where Do I Find Our VERA Data?

**ARC - VERA Model 2022 Reports**

- VERA 2022 Patient Classification Hierarchy with Prices (AA)
  Download in Excel

- VERA 2022 Patient Classification Handbook

- Table 2 - FY 2022 Network GP Allocations: VERA Components (AA)
  Download in Excel

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**FY 2022 Advance Appropriation Network Funding Allocations**

- Table 1 FY 2021 Total Available Network Funding
- Table 1a FY 2022 VERA Estimated Total Available Network Funding Compared to FY 2021
- Table 1b FY 2022 VERA Estimated Specific Purpose Funding Level
- Table 2 FY 2022 Network GP Allocations with President's Budget Medical Community Care Spread included
- Table 2a FY 2022 Network General Purpose Allocations: VERA Components $55,673,554,762 Compared to FY 2021 General Purpose Allocations
- Table 2b FY 2021 Network General Purpose Allocations: VERA Components Allocations
- Table 3 FY 2022 VERA General Purpose Allocations in Medical Care Appropriations Three Account Structure
- Table 3a FY 2021 VERA General Purpose Additional Allocations in Medical Care Appropriations Three Account Structure
- Table 4 FY 2022 VERA Basic and Complex Care Allocations
- Table 4a FY 2022 VERA High Cost Allocations
- Table 4b FY 2022 VERA High cost Patients (PRPs)
- Table 5 FY 2022 VERA Pro-Rated Persons (PRPs) Workload
- Table 6 FY 2022 VERA, Labor Index, Research, & Education Support
- Table 7 FY 2022 VERA Research Support Back-up Data and Allocations
- Table 8 Estimated Medical Care Collections Fund (MCCF), Other Collections & Medical Community Care (MCC)
- Table 9 FY 2022 VERA: Medical Facilities (D182), Lease Funding and Non-Recurring Maintenance (NRM) Funding
- Table 10 FY 2022 Medicare Adjustments
- Table 11 FY 2022 Beneficiary Travel Adjustments
Where Do I Find Our VERA Data?

VERA 2022 MODEL

General Back-up Information

1. High Cost Patient Adjustments (All Price Groups)
   Includes All Price Groups 1-10, 11 (Cost >$156,470) and 10.5 (Cost >$434,000)
   Network Network by Fac

2. High Cost Patient Adjustments (Price Groups 1-10, 11)
   Includes Only Price Groups 1-10, 11 (Cost >$156,470)
   Network Network by Fac

3. High Cost Patient Adjustments (Price Group 10.5)
   Includes Price Group 10.5 Only (Cost >$434,000)
   Network Network by Fac

Research

FY20 RDIS Detail by VISN and Station

Labor

1. FY20 Salary Information for VERA 2022
2. FY20 Labor Budget Object Codes for VERA 2022
3. Labor Index for Pay Periods 1, 2, 3 and 4 by Subaccount for each VISN
4. Labor Index for Pay Periods 1, 2, 3 and 4 by Subaccount - VISN by Facility

Education

1. 2022 OAA Education FTE as of 24Jan22
   Download Workbook

ARCHIVED Reports (2021-2010)

Allocation Resource Center
100 Grandview Road, Suite 114 Braintree, MA 02184-2686
Telephone 781-849-1837 • FAX 781-849-0306
What Contributes to Research VERA

Actual research award dollars are the factor used for determining Research VERA support dollars, with weighted value of the actual grant dollars using the following criteria:

- **100%** VA Administered (including QUERI and ORD Intramural)
- **100%** NPC-Administered (called “VA-Administered-Not VA”)*
- **75%** Non-VA funded, non-VA administered, peer-reviewed research**
- **25%** Non-VA funded or administered and non-peer reviewed**
- **0%** Clinical Center (CESAMH, MIRECC)

The sum of the weighted values is used in the VERA model is referred to as the discounted research grant dollars.

*not separated out in its own column in some earlier archive report years

**affiliate university
## FY 2022 VERA Research Support Back-Up Data and Allocations

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<th>Queri</th>
<th>VA Admin</th>
<th>VA Admin Not VA</th>
<th>Not VA Admin PR undiscounted</th>
<th>Not VA Admin PR discounted @75%</th>
<th>Not VA Admin NPR undiscounted</th>
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</table>
Research VERA Model Used in San Diego

**FTE-Related Costs:**
- **Administrative Personnel with Direct Research Time (either full/part-time)**
  - Charged as actual research effort
- **Fractional Support of Other Services to Process Research-Related Business**
  - Estimated to be in proportion to Research FTE (VA-paid, IPAs, WOCs) relative to total Medical Center FTE
- **Fractional Support of Fiscal Service**
  - Estimated to be a proportion of Research Service Budget (101 and all awards) PLUS Research VERA, relative to total Medical Center Budget
- **Fractional Support of Other Services to Support Research Physical Plant**
  - Estimated to be a proportion of research space to total facility space
- **Research Time Mapping of Clinicians** (including MDs, Psychologists, SW, PharmD, Nurses)
  - Data drawn directly from DSS mapping of research time allocations by clinical service

**Other Costs:**
- Clinical procedures for research (if not charged to grant as direct cost, CRADA-related costs are always charged to contract)
- Leased Space
- Maintenance/Service Contracts, Major Repair/Upgrade Costs (if not funded by special funds)
Research VERA Model Used in San Diego

• Administrative Personnel with Direct Research Time
  • Research Admin/Compliance (FTE to support FT positions on Research Org Chart)
  • ACOS R&D
  • Research Pharmacy Tech
  • Office of Research Agreements Management
  • Privacy Officer (0.25 FTE)
  • Research Compliance Officer
  • Research Compliance Auditor
Research VERA Model Used in San Diego

- Fractional Support of Other Services to Process Research-Related Business
  - Human Resources (this would change under centralized Research HR)
  - COS and Director’s Office
  - Medical Records
  - Informatics
  - Controlled Substance Inspections
  - Education
  - Patient Advocate
  - Police
Research VERA Model Used in San Diego

• Fractional Support of Other Services to Support Research Physical Plant
  • Engineering
  • Environmental Management Services
  • Logistics
  • Facility Environmental Health & Safety
**VA San Diego Research Time Mapping Policy**

**Protected Time in San Diego**

- Clear roles and responsibilities for protected time processes
- Clear expectations for minimum and maximum protected time allocations
- Detailed procedures for authorization and allocation of time:
  - Multiple Funding Sources
  - Co-Investigators
  - VA vs. NPC-Administered vs. Affiliate Funding
  - Industry-Sponsored Research
  - Start-Up and Bridge/Gap Research Time
# VA ORD Guidance for Protected Time for Research Staff

(last updated December 2020)

VHA Directive 1065 Productivity and Staffing Guidance for Specialty Provider Group Practice specifies that CRADO of the Office of Research and Development is responsible for providing VA medical facilities with guidance on protected research time required for various research activities. The Guidance will be posted on the OPES Provider Specialty Practice Management website at [http://pees.vscv.med.va.gov/Peases/Provider-Specialty-Practice-Management.aspx](http://pees.vscv.med.va.gov/Peases/Provider-Specialty-Practice-Management.aspx), and ORD includes this Guidance below. **NOTE:** The OPES is an internal VA website that is not available to the public.

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<th>Research - Mapping Allocations Research Activity</th>
<th>Recommended FTEE Allocation</th>
<th>Recommended Hours per week</th>
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<td>PI NIH RR1*</td>
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<td>PI Industry-sponsored Clinical Study</td>
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VA San Diego Research Time Mapping Responsibilities

❖ Principal Investigators:
  ❖ Obtain approval from Clinical Section/Service Chief for all time to be allocated to research prior to engaging in the research on VA time

❖ R&D Committee and Applicable Subcommittees:
  ❖ Evaluate all proposed research projects, including as applicable sufficient time commitment of investigators to accomplish the project

❖ Service/Section Chiefs:
  ❖ Discuss with PIs, and provide Service-level approval for protected time mapped to research
  ❖ Obtain approval from Chief of Staff for the protected time allocation
  ❖ Effective allocation of temporary 1/8ths provided to Service to effectively support the clinical mission

❖ ACOS R&D:
  ❖ Oversee the accurate and timely completion of RDIS report that determines Research VERA allocation
  ❖ Provide reports as needed to facility leadership and Service Chiefs regarding research funding of individual PIs at a service-specific level
VA San Diego Research Time Mapping Policy

❖ Categories Including in San Diego Policy:
  ❖ VA Intramural Funded Research (Merit, CDA, SPiRE, Pilot, CSP, etc)
    ❖ Includes Co-I allowances, not included in national guidance
  ❖ Extramural-Funded Peer-Reviewed Research
    ❖ When PI or Co-I is doing work on VA time, NOT separately compensated
  ❖ Non-Peer-Reviewed Extramural-Funded Research
    ❖ Includes CRADAs, but only where sponsor will not agree to reimburse PI effort as part of the NPC-administered budget for the project
  ❖ Non-funded Research, including Pilot Data Collection, Bridge Time
    ❖ Generally must be geared towards ultimate application for funding
  ❖ New Investigators
    ❖ Typically initial agreements written for periods of 1-3 years depending on credentials of clinician at hire (e.g. funding already in JIT, application under review, applications need development)
  ❖ Research Support Activities (Committee Chairs, Membership, Editor Role)
Clinical investigators’ “protected time” figures for specific research-related activities represent maximum time allowances for a given category of activity. Salaried clinical staff may perform research or research-related activities and will be granted protected time according to the nature of such activities, consistent with the VERA research support component.

In general, the amount of VA effort allocated to research will not exceed 60% of the total VA time (e.g. 3/8ths for a 5/8ths clinician with Merit), although exceptions may occur.

Under special circumstances, the protected time allowance may be increased if a particular research activity is deemed critical to accomplish the VA San Diego Healthcare System research mission, i.e., as evaluated by the R&D Committee, Service Chief, Associate Chief of Staff (ACOS)/R&D, and approved by the Chief of Staff.

It is expected for Merit-eligible clinician investigators that at least 2/8th of any total VA effort would remain mapped to clinical time, unless a specific local exception has been requested and approved by the Clinical Service Chief and Chief of Staff.
Special Considerations:

- PI of 2+ Merits may receive some incremental increase in maximum protected time, generally no more than 5/8ths for 2 Awards, 6/8ths for 3+ awards.
  - Note that Pilot Awards and SPiRE Awards are at reduced funding levels relative to a Merit Award, and PI effort allocation for these awards may therefore appropriately be less, e.g. 1/8<sup>th</sup>-2/8<sup>th</sup> (0.125-0.250).
  - This ensures that minimum clinical effort is maintained (again, exceptions can be made in well-justified cases with approval of Section/Service Chief and Chief of Staff).

- Each given funded award must look at Co-Investigator (Co-I) time collectively with PI time, suggested minimum 10% effort declared in the Award budget for protected time to be considered for a Co-I.
  - Maximum of 4/8ths effort available to be divided among PI and Co-Is for a Merit-level award.
  - Pilot and SPiRE Awards may be limited to at most 2/8ths between PI and Co-Is given their more limited scope and amount of funding.
• Time is not Mapped DIRECTLY to Funding of a Given PI, rather Facility-Wide Averages are Utilized for Given Activities:
  – New Funding won’t produce VERA until 2 years later, funding ending this year will still generate VERA for 2 years
  – Total Research VERA $ Available can vary year-to-year (multiplier goes up and down depending on how much funding is reported across all facilities, what Congress sets as the VERA allocation (used to equal 100% of ORD total annual research budget, now about 85%)
  – All Awards are not created equal
    • CSP Budgets vary study-to-study
    • Clinician vs. non-clinician BLR&D budgets
    • BLR&D Merits have lower direct costs (and VERA) than other services currently (this may need to change in re-alignment)
  – Clinician salary/benefit costs vary by specialty
VA San Diego Research Time Mapping Procedures

- Status as a VERA-generating or non-VERA generating Service shall be validated at least annually in January, utilizing the data from the RDIS report of the prior fiscal year.

- **Research VERA-Generating Services:** Defined as services that have clinician investigators who generate funded research projects as Principal Investigators (PIs).

- **Services Not Generating Research VERA Currently:** For services that do not have clinician investigator PIs that hold funding that generates Research VERA at present, allocation of research time may still be appropriate for certain categories of activity, including co-investigator or research support (e.g. Nurse, Pharmacist) roles on funding held by PIs in other services, Career Development Award (CDA) Mentorship on a CDA Award from a mentee in another service, service on Research Committees, or time to develop an initial proposal for funding/collect pilot data.
VA San Diego Research Time Mapping Procedures

❖ Establishing an Average Research VERA Expectation Per FTE

❖ For purposes of this estimation process, the most common intramural funding mechanism, the VA Merit Award, is utilized.

❖ The average Research VERA received for every $1 dollar of total (undiscounted) funding reported in the annual RDIS reports for FY19-FY21 was $0.63.

❖ With clinician PI VA Merit Awards as of Jan 2022 at VASDHS averaging $230,000 in value (16 BLR&D Merits at $165,000 annual direct costs, 15 HSR&D/RR&D/CSR&D Merits at $300,000 annual direct costs), the VERA produced by the average clinician PI Merit is $145,100.

❖ Per VA San Diego Policy, a VA Merit Award is given a maximum allowance of 3/8th research time (0.375 FTE) for the PI, up to 4/8th total including Co-Is.

❖ Therefore 1.0 clinician PI FTE mapped to Research would be expected to produce about $385,000 in Research VERA on average, with the average cost of that FTE being $330,000.
Research Clinical Time Mapping at VASDHS averages about 45-55% of total VERA in a given year.

We see that a typical Merit for a clinician produces MORE VERA on average than the FTE mapped to it, but not enough to account for the other 50% of expected VERA Costs.

Also still need to account for new investigator start-up time, bridge funding time, committee support time, and clinician co-Investigator time (including time of clinicians in non-VERA-generating services).
Where Does the Rest of It Come From: VERA Sources that Don’t Require Protected Time:

- Extramural awards where effort is provided on non-VA time
  - US Code 209 Issue makes this problematic at some sites
- A robust non-clinician PI cohort (currently numbering 50 funded PIs at VA San Diego, equal to the clinician cohort), generate the same research VERA for RR&D/CSR&D/HSR&D as clinician Merits, but don’t have any associated VERA time mapping costs for PI
  - BLR&D Merits for non-clinicians actually produce MORE VERA than a clinician BLR&D Merit, as the non-clinician gets 5/8ths or more salary in addition to the annual $165,000 budget
- Therefore, I have argued to BLR&D over the years that non-clinician eligibility, rather than being seen as in competition to funding for clinician Merits, actually helps foster recruitment and retention of clinician scientists by helping to fund start-up and bridge protected time
Protected Time for Non-VERA-Generating Individuals:

- Bridge or Start-Up Time for PIs without current funding support within VERA-Generating Services

- All Categories of Research Protected Time for individuals from Non-VERA Generating Services

- Utilize a Research Effort Agreement to document the duration of time provided, milestones to be met, criteria for re-evaluation, extension, etc.

  - The effort agreement is written to allow services to utilize it for documenting funded protected-time also, optional

  - Use is required when supporting time of an individual that is not directly linked to funding held by the given individual
# VASDHS Research Effort Agreement

The **Research Effort Agreement** characterizes VA providers’ time commitment towards research. The information in this document should assist in clarifying VA timekeeping and labor mapping associated with these research activities.

VASDHS providers with **VA intramural research funding** can participate in research activities during a VA Tour-of-Duty. For example, a VA Merit Review Award (VA Merit) typically is accompanied by direct salary support (typically 3/8) for time spent in research activities related to the VA Merit, provided through Research VERA received for the funded work. The provider’s Tour-of-Duty should include time for both clinical and research activities.

1. Establishing funding for a new VA Merit, Career Development Award, or CSP study plan.
2. Re-establishing funding for a previous VA Merit (during a funding “Gap”); or
3. An existing (or planned) VA-approved clinical trial, research project, or research program (e.g. VMRF-administered CRADA or extramural funded award).

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<th>Provider’s Name</th>
<th>End Date</th>
<th>FUNDING Thru:</th>
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<td>VA</td>
<td>VMRF*</td>
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<tr>
<th>Dr. ___________________________ is authorized to participate in the following currently funded activities:</th>
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<th>TITLE</th>
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(attach additional pages if needed)

Time allocated to these activities shall be approximately ________ hrs./wk. **

(# Hours)

Some of these activities may occur at/in:

__________________________

(If applicable, list Off-Site locations and attach appropriate documentation in support, see next page)

Time allocated to the off-site activities shall be limited to ________ hrs./wk. in accordance with the justified reason(s). **

(# Hours)

If these activities are in pursuit of future funding, describe the project:

Title/Brief Description: ____________________________

Planned Funding Source (e.g., VA Merit, NIH, CRADA, DoD, etc.):

Planned Submission Date: ______/_____/______ **This agreement is valid until ______/_____/______.

* For any time allocated above for research with extramural funding support (VMRF-administered): The provider cannot receive non-VA salary support from another source for time spent in these research activities.

**If funding for the provider’s research activities is **lost and initial or renewed funding not obtained** during the specified period, one of the following actions should occur:
1) Extend or alter the Research Effort Agreement with revised justification/timeline/plans.

2) Increase the provider’s clinical (or other) activities and adjust his/her labor mapping to account for the time previously assigned to research activities; or

3) Decrease the provider’s overall VA commitment (8ths).

***If funding for the provider’s research activities is obtained or renewed during the specified period, the provider’s labor mapping should be reviewed, and a new Research Effort Agreement created as appropriate.

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<th>Research Service Chief Verification of Research Project Details</th>
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Guidance on submitting justification for Research Work in Off-Site Locations:

a. If funded by VA Merit attach approved off-site waiver specific to each funded project and note that:
   (1) Off-site waivers are project-specific and expire when the VA funding ends.
   (2) Off-site activities are limited to those specified on the off-site waiver; time spent in off-site activities must be commensurate with the ratio of on-site to off-site work.

b. If funded by VMRF or unfunded provide a detailed justification of why research activity must be conducted off-site and cannot be accomplished at the VA facility.
Challenges

❖ Sites with Limited VERA—does just the ACOS R&D and some other Admin personnel salary equal/exceed available VERA?
  ❖ Facility and Clinician Researchers both contribute to the “gap” to build towards VERA growth?
  ❖ How can ORD support such sites in growing a protected time pool?
❖ US Code 209 represents major challenge currently to:
  ❖ NPCs paying direct effort to PIs on awards
  ❖ Sites where the academic affiliate is a private institution
❖ Sites with Remote Affiliates, or Affiliates with Limited Engagement with VA: More Difficult to Grow PI Base (Clinician and Non-Clinician)
  ❖ Strategies to enhance affiliate relationships-GAO Report Workgroup White Paper
  ❖ Research Affiliate Agreements—need not be same as education affiliate-GAO Workgroup recommendation to ORD
QUESTIONS & COMMENTS?