

VA Research Processes and Protections

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Deputy CRADO - Enterprise Support

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VA ORD is responsible for the execution of VA's research mission

VA Research Mission



- **To improve Veterans' health** and well-being via basic, translational, clinical, health services, and rehabilitation research. Apply scientific knowledge to develop effective individualized care solutions for Veterans



- **To attract, train, and retain the highest-caliber investigators**, and nurture their development as leaders in their fields



- **To assure a culture of professionalism, collaboration, accountability, and the highest regard for research volunteers' safety and privacy**

ORD 5 Strategic Priorities

- 1 Increase Veteran’s access to high-quality clinical trials
- 2 Increase the substantial real-world impact of VA research
- 3 Put VA data to work for Veterans
- 4 Actively promote diversity, equity, and inclusion within our sphere of influence
- 5 Build community through VA research

For more information, visit: [VA Strategic Priorities](#)

VA Research Funded by Different Sources



VA Research
Appropriation



Other Federal Agencies



Industry



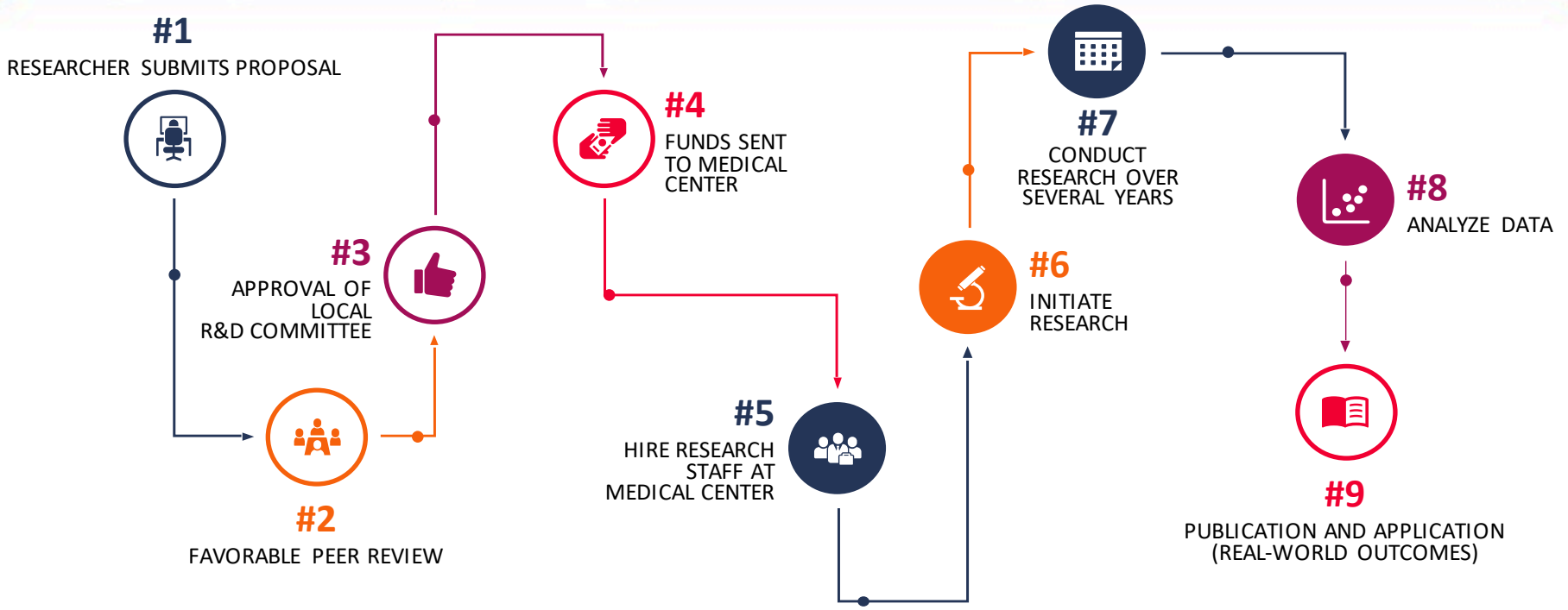
Non-Profits



VA ORD manages congressional research appropriations and distributes \$750M to research studies at VA hospitals across the country

**Collectively make up the
\$2B research budget**

ORD funds research across the VA Medical System, this is the journey of a successful VA-funded research project



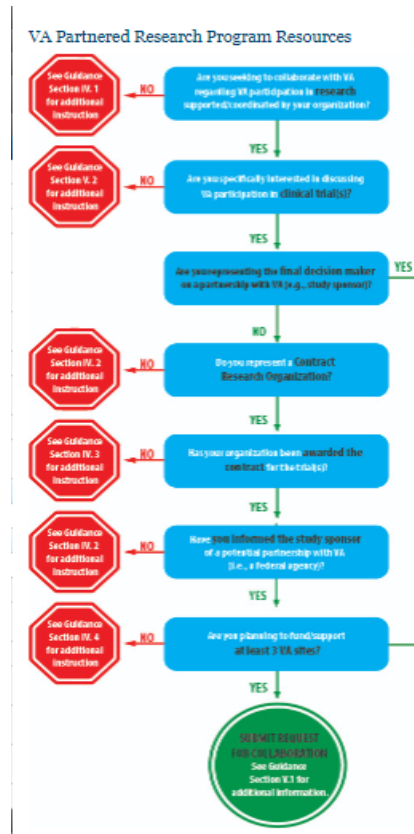
- 4,600 research funded FTEs
- 12,000+ WOC/IPAs
- 2,000 proposals per year
- 550 new projects funded per year

Partnered Research Program

• The “Front Door” for Industry Clinical Trials

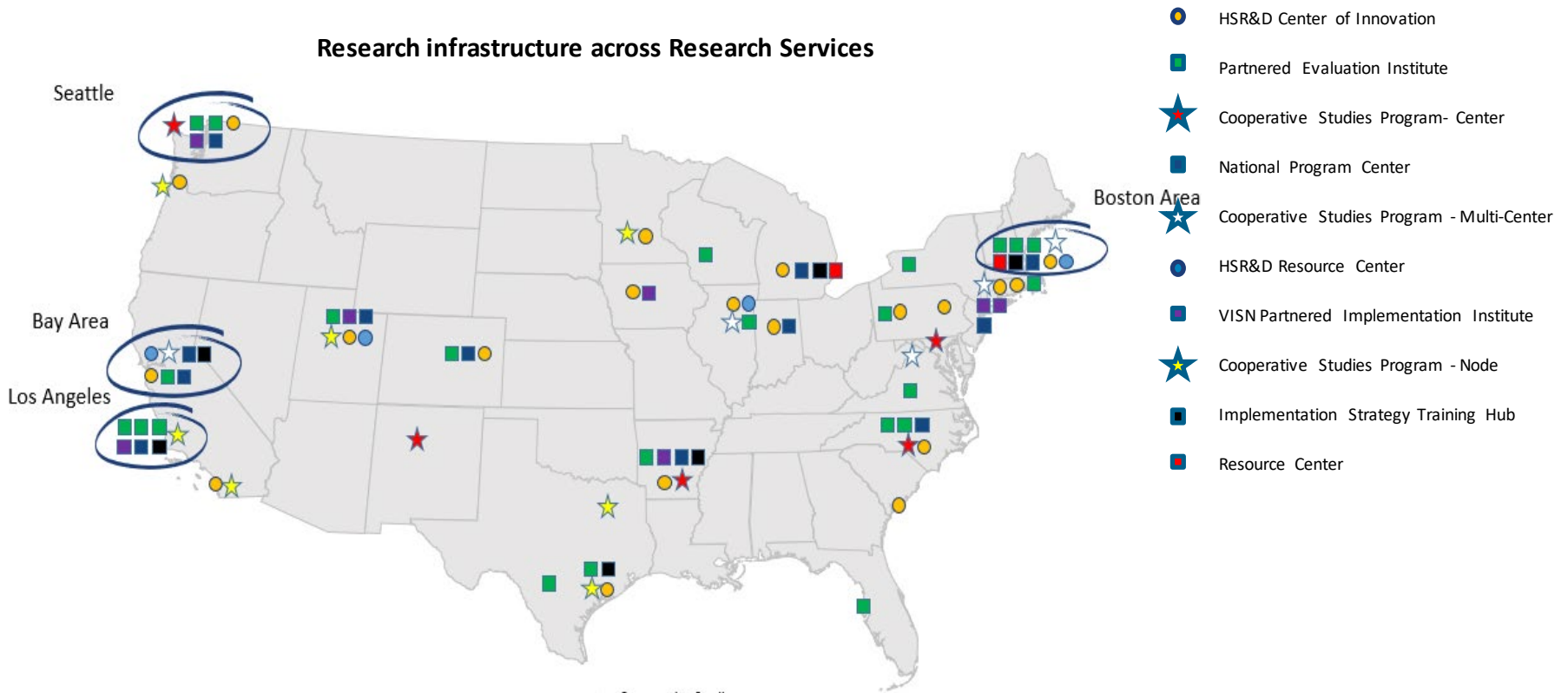
- Serving as the entry point for external organizations (i.e., study sponsors and CROs) seeking to conduct multisite clinical trials within the VA healthcare system.
- Connecting interested organizations with appropriate VA resources/stakeholders to evaluate potential research collaborations.
- Offering guidance and support to multisite clinical trial stakeholders with respect to select operational activities

Website: [VA Partnered Research Program](#)



VA ORD research infrastructure spans the whole country

Research infrastructure across Research Services





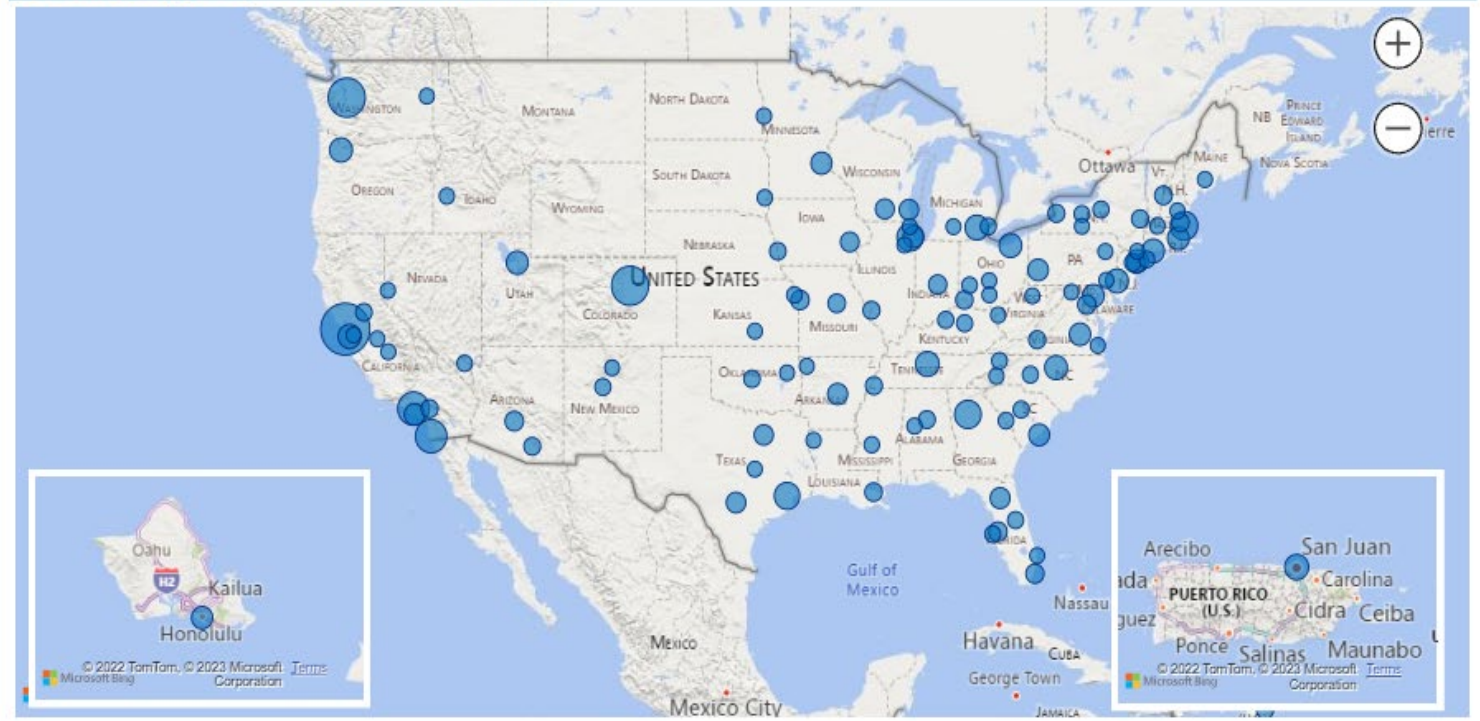
CRADO | ACTIVE PROJECT DETAIL



U.S. Department of Veterans Affairs

Projects	Active Packages	Sponsors	VA Sites	PIs
19960	30983	2692	110	7089

Active Packages by Institution Location ?



Search

VISN

All

Institution Location

All

ORD Funding Indicator

All

Funding Type

All

Board Type

All

IRB Project Risk Level

All

Clear All Filters



VISN
All

Institution Location
All

ORD Funding Indicator
All

Funding Type
All

Board Type
All

IRB Project Risk Level
All

Clear All Filters

Projects	Active Packages	Sponsors	VA Sites	PIs
177	274	44	38	101

Active Packages by Institution Location



THE CRADO DASHBOARD

CRADO Active Projects Reporting | Data updated 1/29/23

File | Export | Share | Get insights | Subscribe

VAIRRS VA Innovation and Research Review System

CRADO | VISN SUMMARY

VA U.S. Department of Veterans Affairs

Search

VISN
All

Institution Location
All

ORD Funding Indicator
All

Funding Type
All

Board Type
All

IRB Project Risk Level
All

Drill Through Selection

Clear All Filters

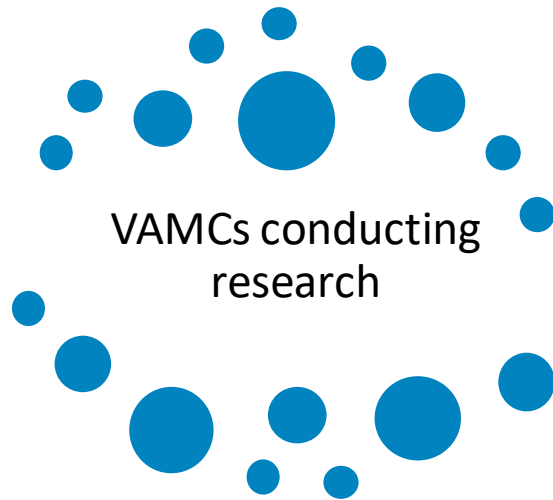
Active Projects	Active Packages	Sponsors	VA Sites	PIs
19960	30983	2692	110	7089

Institution Location	NIH	ORD	Other Federal Agency	Other Government, Private Donor, or Academic Institution	Private Proprietary Company	Voluntary Agency/Foundation
Albany, NY		2	3		1	7
Albuquerque, NM		6	13	3		8
Ann Arbor, MI		40	132	21	12	8
Asheville, NC		1	6			2
Augusta, GA		6	17		1	
Augusta, ME		2	4		1	
Baltimore, MD		35	109	7	2	6
Total		1967	4783	748	764	1047

Project ID	Title	Institution Location	Board Type(s)
203760	ACT...	Little Rock, AR	IRB; R&DC
203938	G...	Little Rock, AR	Research Admin
203958	M...	Little Rock, AR	Research Admin
204203	A...	Little Rock, AR	R&DC; Research Safety
204273	M...	Little Rock, AR	IRB; Research Safety; R&D...
204324	(L...	Little Rock, AR	Research Admin
204333	P...	Little Rock, AR	R&DC; IRB
214547	A...	Tuscaloosa, AL	R&DC
219771	T...	Tuscaloosa, AL	IRB
224756	C...	Little Rock, AR	Research Safety; R&DC

Titles shielded for potential Intellectual Property Concerns

Transforming into a Research Enterprise to Increase VA Research Real-World Impact

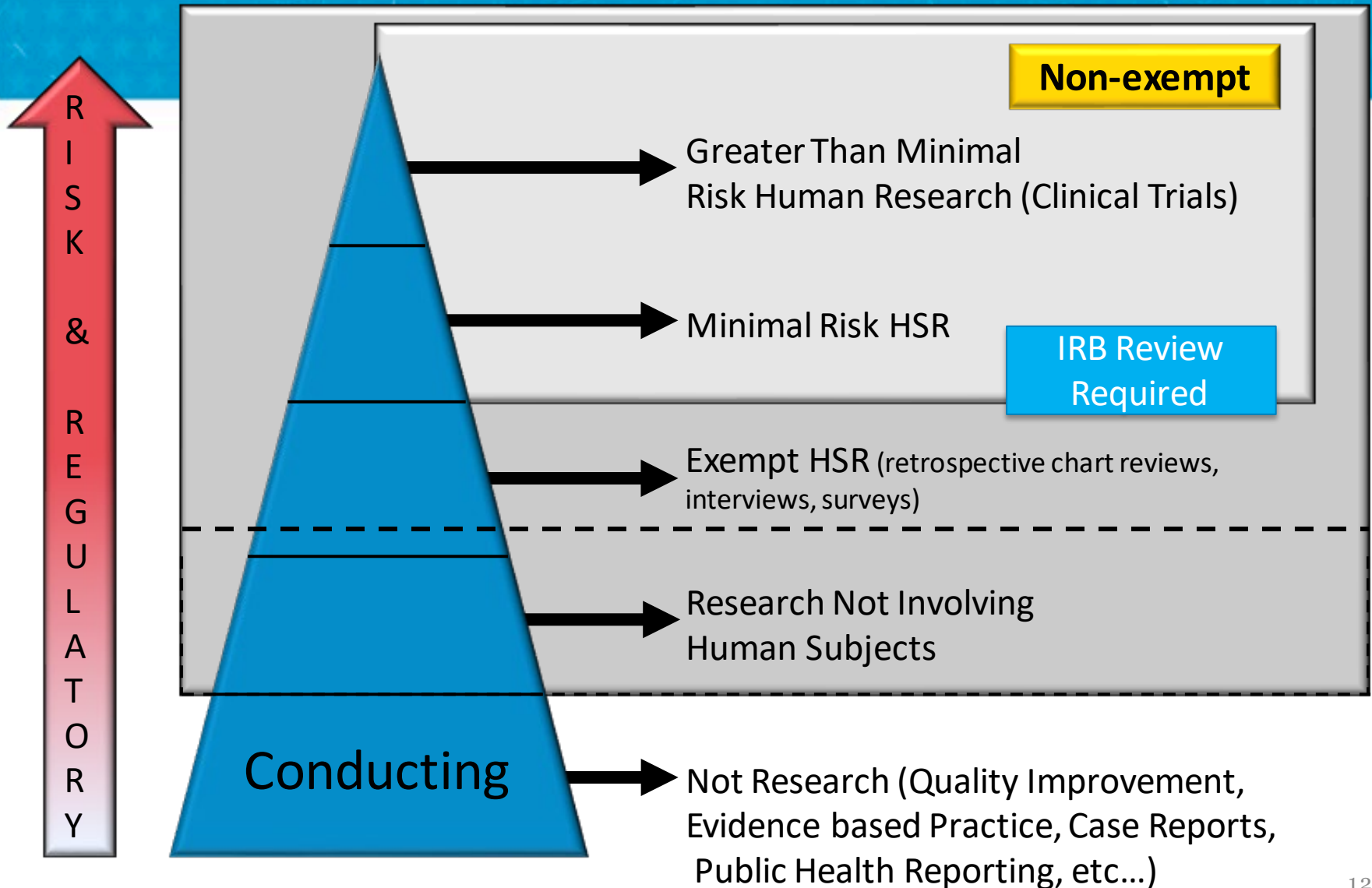


~100 VA medical centers (VAMCs) independently conducting research

Office of Research & Development's primary roles are funding and policy.

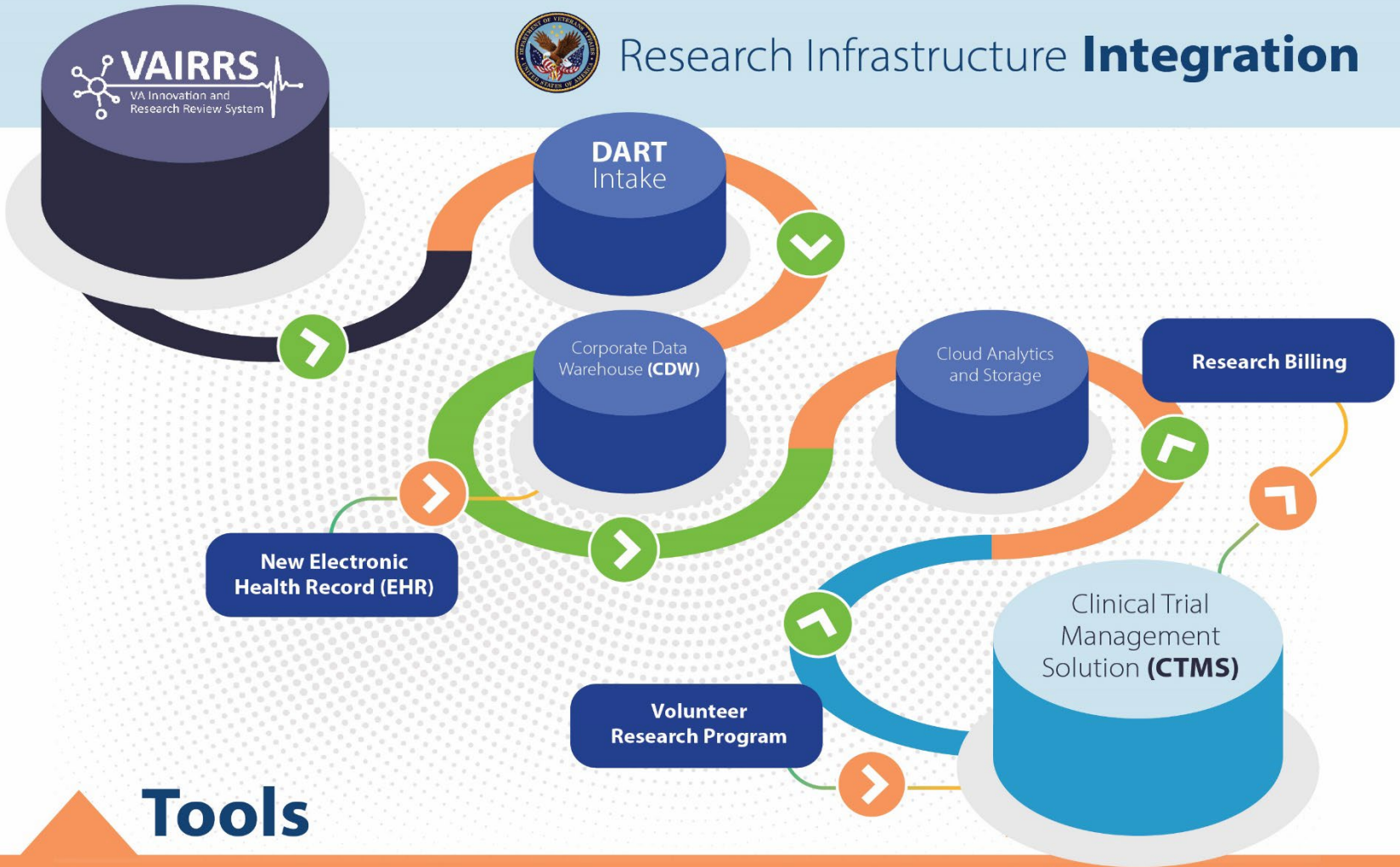
Integrated whole in which we work as an enterprise

Research Pyramid





Research Infrastructure **Integration**



Tools



VA RedCap

FIND Pro

DocuSign

VAEDA

Qualtrics

Box.com



SOFTWARE LIBRARY



RESEARCH LAW EXPLORER

How to Find Out Information on ORD Funded Clinical Trials?

- [Gulf War Research Program \(va.gov\)](#)

Gulf War Era Cohort and Biorepository Pilot Project (CSP #585)

The primary objective of this project is to develop a research cohort of Veterans who served during the 1990-1991 Gulf War Era, and a biorepository, that can be accessed by investigators who want to study the health and health conditions of this population. The first phase of the pilot project assessed the feasibility of and evaluated methods for recruitment, blood collection, tracking, and data storage to inform a full scale project and future research activities. This phase was completed in May 2016, and the results are being analyzed. Interested investigators may submit requests to access the data and/or specimens through the [CSPEC-Durham Data and Specimen Repository](#).

The team is currently implementing the second phase of the pilot project which involves qualitative research that aims to better understand Gulf War Era Veterans' perspectives regarding participating in research. These findings will help inform and improve future research projects involving this population.

Study Chair: Dawn Provenzale, MD, MS

For additional information, please visit the [CSP #585 website](#).

Genomics of Gulf War Illness in Veterans (CSP #2006)

The primary objective of this study is to evaluate potential genetic risk factors for Gulf War Illness by conducting a genome-wide association study. Data will be collected under the [Million Veterans Program \(MVP\)](#) protocol. This study leverages the rich resources of the Million Veterans Program; identifying Gulf War I Era Veterans, administering a follow up survey to those Veterans and obtaining data on their Gulf War experience and subsequent health conditions.

Study Chairs: Dawn Provenzale, MD, MS; Drew Helmer, MD, MPH

How to Find Out Information on Other GWI Clinical Trials?

- **ClinicalTrials.gov**

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	Assessing Neuroinflammation in GWI Using MRS	<ul style="list-style-type: none"> • Gulf War Syndrome 	<ul style="list-style-type: none"> • Procedure: Magnetic Resonance Spectroscopic Imaging • Procedure: Blood draw 	<ul style="list-style-type: none"> • University of Alabama at Birmingham Birmingham, Alabama, United States
2	<input type="checkbox"/>	Not yet recruiting	GHRT in Veterans With Gulf War Illness and AGHD	<ul style="list-style-type: none"> • Gulf War Syndrome • Adult Growth Hormone Deficiency 	<ul style="list-style-type: none"> • Drug: Recombinant human growth hormone • Drug: Placebo 	<ul style="list-style-type: none"> • Michael E. DeBakey VA Medical Center Houston, Texas, United States • VA Puget Sound Healthcare System Seattle, Washington, United States
3	<input type="checkbox"/>	Not yet recruiting	GWICTIC: NAC Mechanistic Study in Gulf War Veterans	<ul style="list-style-type: none"> • Gulf War Syndrome 	<ul style="list-style-type: none"> • Drug: N-Acetyl Cysteine • Drug: Placebo 	<ul style="list-style-type: none"> • VA Palo Alto Health Care System War Related Illness and Injury Study Center Palo Alto, California, United States • Nova Southeastern University Fort Lauderdale, Florida, United States • Boston University Medical School Boston, Massachusetts, United States • (and 3 more...)
4	<input type="checkbox"/>	Recruiting	Long Term Efficacy of Neuronavigation Guided rTMS in Alleviating Gulf War Illness Related Headaches and Pain Symptoms	<ul style="list-style-type: none"> • Gulf War Syndrome • Gulf War Illness • Headache • (and 2 more...) 	<ul style="list-style-type: none"> • Device: Transcranial Magnetic Stimulation • Device: Sham Transcranial Magnetic Stimulation 	<ul style="list-style-type: none"> • VA Palo Alto Palo Alto, California, United States • VA San Diego Healthcare System San Diego, California, United States • VA Atlanta Decatur, Georgia, United States

[Search of: Recruiting, Not yet recruiting Studies | Gulf War Syndrome | United States - List Results - ClinicalTrials.gov](#)



VA Research Volunteer Program



What is the Research Volunteer Program?

VA-wide, centrally managed program to link research volunteers to VA research resources and research opportunities.

Why are we starting this Research Volunteer Program?

VA research is done to improve Veteran healthcare and well-being of our Veteran population. The program will put Veterans in touch with VA research that matters to them; without Veteran participation we would not have a research program.

What is the goal of the program?

Creating and sustaining a modernized connection between VA Research and Research Volunteers.

Other Ways for Researchers to Access Data

- Informed Consent for Future Use
 - Data are saved
 - Similar projects
 - Any type of project
 - Restrictions defined (identified or not), leaves the VA or not
- Surveys completed (implied consent)
 - Information that defines use of the data

HIPAA Authorization Alteration/Waiver

- The use or disclosure of protected health information involves **no more than a minimal risk to the privacy of individuals**, based on, at least, the presence of the following elements:
 - an adequate plan to protect the identifiers from improper use and disclosure;
 - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- The research could not practicably be conducted **without the waiver or alteration; *and***
- The research could not practicably be conducted **without access to and use of the protected health information.**





BACK UP SLIDES

What are the benefits of operating as a Research Enterprise?



Improving Veteran well-being by more efficiently delivering innovations that matter to them and expanding access to high-quality clinical studies



Providing investigators with the ability to easily access data, research resources, staff, and other support they need to readily conduct research that enhances the lives of Veterans



Making it easier for external organizations to partner with VA Research, enabling all organizations to achieve their goals when collaborating together



Promoting the continued success of VA Research by empowering ORD to most effectively support research through staff-led strategic initiatives

VA Research Enterprise Vision

The VA Research Enterprise is the entire research workforce cooperating to advance Veteran wellbeing. The VA Research Enterprise aspires to embody the following qualities:



Unique Value Proposition: Leverage our position as the only Federal research entity devoted to Veterans' interests and being embedded in the nation's largest integrated healthcare system



Operational Excellence: Operates with streamlined processes, effective collaboration, high-quality customer service, and appropriate resources



Engaged People: Composed of a vibrant, diverse research community united in our mission to improve Veterans' well-being through research



Integration: Cultivate relationships and partnerships that accelerate our ability to achieve our mission



Real-world Outcomes: Define our success in terms of tangible real-world improvements in Veterans' health and well-being