



# COVID-19 – VA Cooperative Studies (CSP) Epidemiology Program Research

---

**Dawn Provenzale, MD, MS**  
**Director, CSPEC-Durham**



Veterans | Health Administration  
**Research & Development**

Improving Veterans' Lives  [www.research.va.gov](http://www.research.va.gov)

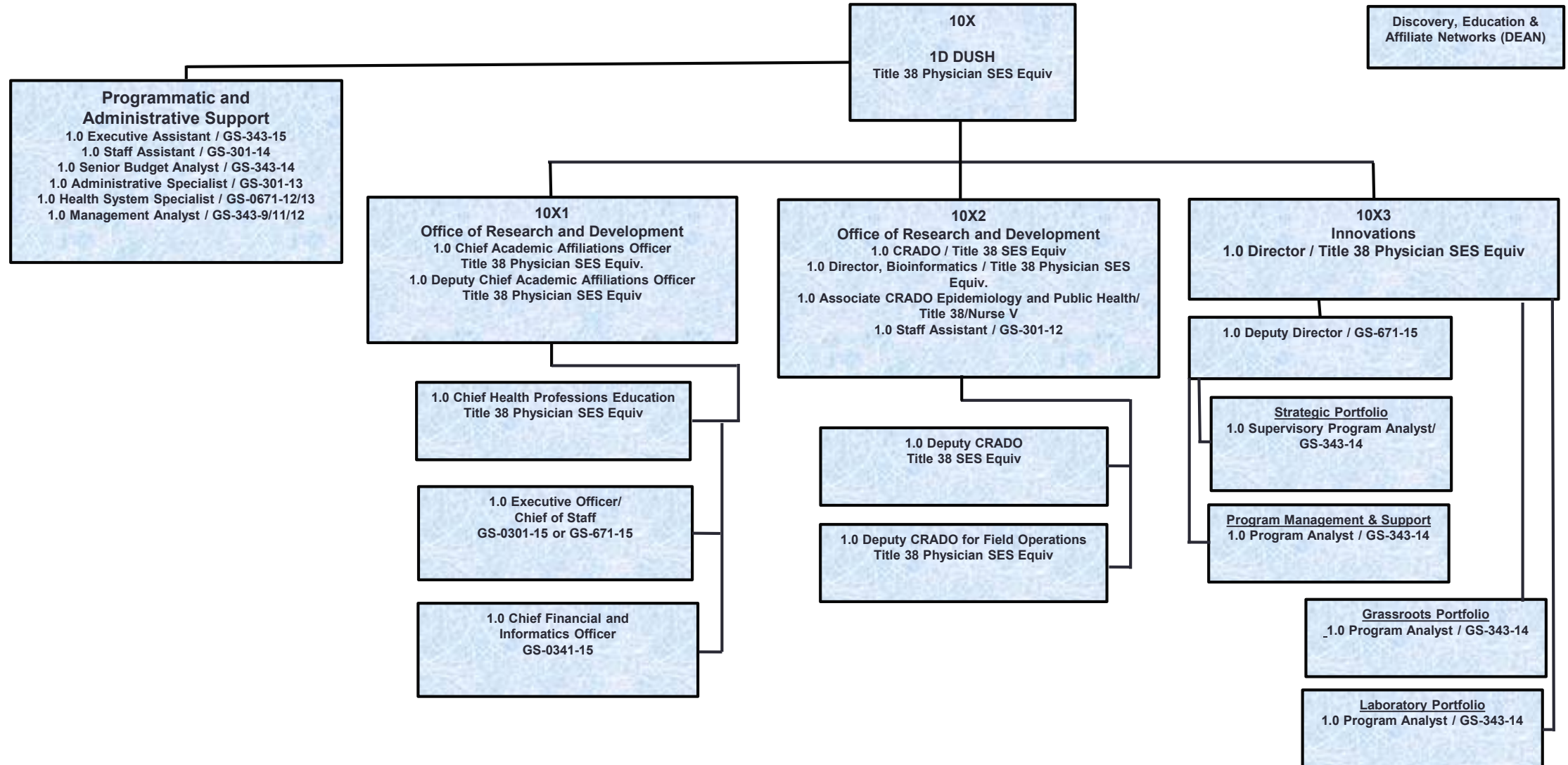
# COVID-19 – VA Cooperative Studies Epidemiology Program Research

## Overview

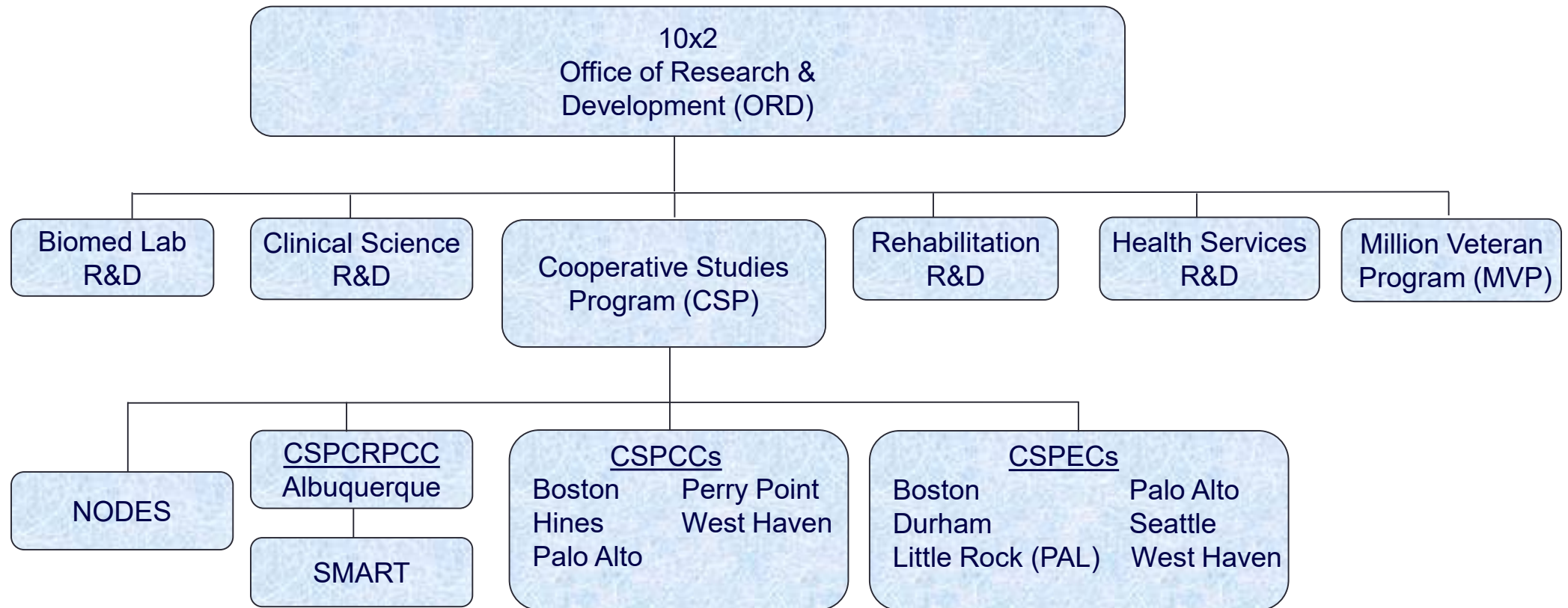
- Office of Research and Development
- VA Cooperative Studies Program (CSP)
- VA CSP Epidemiology Program-COVID-19 studies

# Veterans Health Administration

## Discovery, Education & Affiliate Networks – DEAN (10X)



# VA Cooperative Studies Program Overview



# CSP Epidemiology Studies - Current COVID-19 Cohort Efforts

## VA Epidemiology Program-COVID-19 studies

- EPIC<sup>3</sup> –CSP 2028
- Million Veteran Program (MVP)
- Convalescent Plasma
- RECOVER
- EPICOVID

# Current COVID-19 Cohort Efforts - CSP #2028 (EPIC<sup>3</sup>)

## Epidemiology, Immunology and Clinical Characteristics of COVID-19

- Conducted by CSPEC program in consultation with the DoD, and based on DoD protocol
- Observational cohort of affected and unaffected Veterans who are tested for SARS-CoV-2 infection
- 3 sub-cohorts
  - VHA inpatients with and without COVID-19 (n~1000)
  - VHA outpatients with and without SARS-CoV-2 infection (n~2000)
  - Residents of Community Living Centers (~5-6 Centers)
- 24-month follow-up of each group to address 4 scientific aims
- Viral shedding; immunity development and re-infection; risk factors and clinical course; and transmission
- Status:
  - CIRB protocol approved (May 15<sup>th</sup>, 2020)
  - 6 motivated vanguard sites: Boston, Durham, Palo Alto, Philadelphia, Seattle, and West Haven
  - CIRB LSI applications approved for Durham, Palo Alto, and Seattle sites; local R&D applications in progress
  - 1<sup>st</sup> participant recruitment target date - Fri, June 26<sup>th</sup>

# Current COVID-19 Cohort Efforts - Million Veteran Program

- Million Veteran Program (MVP)
- a national research program to learn how genes, lifestyle, and military exposures affect health and illness.
- Since launching in 2011, over 825,000 Veteran partners have joined one of the world's largest programs on genetics and health.



Enroll as many as 1M Veterans  
into a genetic/health cohort



Specimen for research on any disease or illness



Access to health records



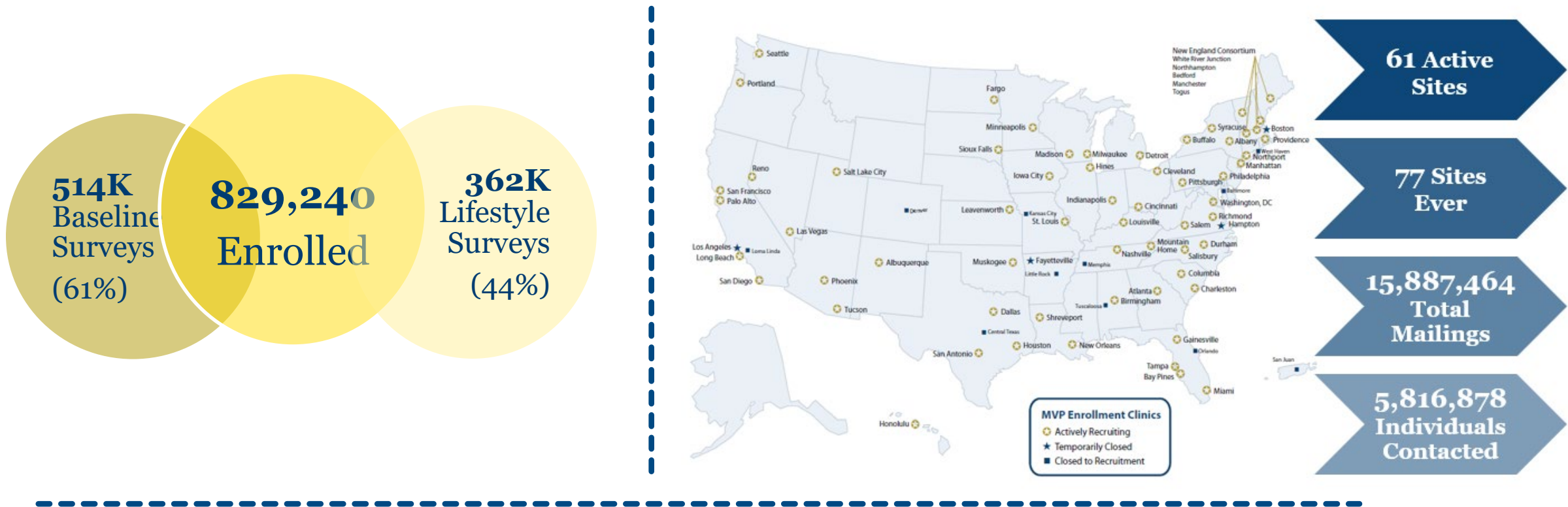
Self-report health & lifestyle information



Re-contact for updates & additional research



# MVP at a Glance



Due to COVID-19, in-person R/E efforts on hold since 03/16/2020.  
MVP Online still operational – R/E staff steering Veterans online

# Current COVID-19 Cohort Efforts - MVP

~15.5K MVP participants tested through VA as of 5/15/20: 1,500 positive (14,000 negative)

## MVP COVID-19 survey data collection

- 30,000 paper surveys mailed on 5/5 to random sample and COVID persons of interest; to date 10,914 completed
- MVP Online Survey launched 5/18; to date 22,482 completed
- Total of 33,396 completed surveys
- Phone campaign underway to increase survey completion
- Additional survey requests will be distributed to non-responders in September

## MVP specimen pilot activities

- Pilots underway for at-home blood collection modalities
  - capillary and dried blood spot technology
  - usability/scalability (among COVID and non-COVID participants)
- Coordination with Holodniy lab (Palo Alto) for processing and serologic testing

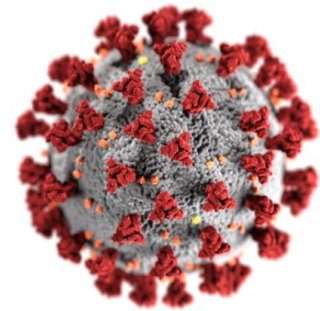
### **MVP partners help VA lead the way for COVID-19 research**

The VA Million Veteran Program (MVP) is partnering with Veterans to respond to the COVID-19 (coronavirus) pandemic. MVP is dedicated to learning more about diseases that impact both Veterans and humankind to help with prevention and treatment. With the outbreak of COVID-19, the health community is working quickly to better understand how to treat and prevent the virus. MVP is ready to help with these efforts.

The MVP COVID-19 Survey provides an opportunity for Veterans to help MVP learn more about their experience with COVID-19, including how the pandemic is affecting their physical and mental health.

By taking the survey today, Veterans can help VA lead the way for COVID-19 research.

[Sign in to take the COVID-19 Survey](#)



# MVP Online For Expanded Enrollment



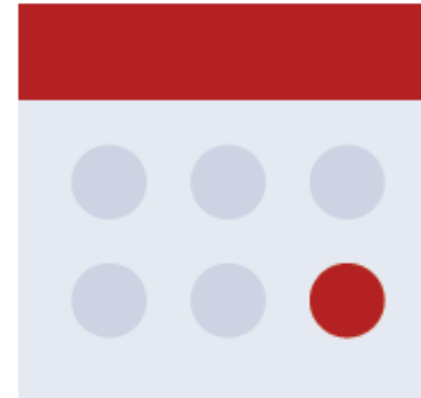
## SIGN IN

using the same credentials as other VA partners (such as My HealthVet or eBenefits).



## COMPLETE

the consent process and allow access to health records.



## SCHEDULE

an MVP visit to provide a blood sample.



## FILL OUT

surveys about health and lifestyle.

**[mvp.va.gov](https://mvp.va.gov)**

Launched 09/19

# Current COVID-19 Cohort Efforts - Convalescent Plasma for Treatment of Veterans with COVID-19

<b>Background</b>	Preliminary evidence shows that use of convalescent plasma (CP) therapy in patients with severe or life-threatening COVID-19 may improve outcomes. Veterans receive CP therapy under the Mayo Clinic Expanded Access Protocol.
<b>Purpose</b>	To identify early signals of efficacy and harm of CP treatment in Veterans with COVID-19 using VA electronic health record (EHR) data
<b>Aims</b>	<ol style="list-style-type: none"><li>1. Examine the short-term impact of CP use and non-use among Veterans with COVID-19 on time to death, discharge, intubation, and extubation</li><li>2. Examine the longer-term impact of CP use and non-use among Veterans with COVID-19 on time to death, discharge, intubation, and extubation as well as other complications</li><li>3. Examine the harm of CP among Veterans with COVID-19</li></ol>
<b>Design</b>	Non-interventional, retrospective exposure-control study in which exposed patients (recipients of CP) are matched to a control population (non-recipients of CP) and followed over time
<b>PIs</b>	J. Michael Gaziano, MD, MPH and Nicholas L. Smith, PhD
<b>Status</b>	Under review by VA Central IRB and local R&D Committees

# Current COVID-19 Cohort Efforts – Research on the Epidemiology of Corona Virus Among VISN 6 VEteRans – (RECOVER) A Collaborative Initiative with State of North Carolina



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL

# Current COVID-19 Cohort Efforts - RECOVER

---

**Purpose:** To develop a Veteran-specific prevalence program that will provide documentation of COVID-19 disease activity and seroprevalence across a broader regional scope and with a particularly vulnerable population to complement county-level programs

---

**Aims:**

- Establish the **prevalence of COVID-19 disease** by conducting self-reported symptom surveys and RT-PCR testing of self-obtained nasopharyngeal swabs
- Establish the **prevalence of population immunity to SARS-CoV-2** by conducting self-obtained serum sampling for serology
- Evaluate the **proportion of asymptomatic and mildly symptomatic COVID illness**
- Evaluate **demographic, geographic, and socioeconomic differences in COVID-19** symptoms, disease, and mitigation strategies

---



# Current COVID-19 Cohort Efforts - RECOVER

## Potential Phased Approach

- 1) Initial pilot phase-- Durham and Salisbury sites, target enrollment=100 for survey, 50-100 for samples;
- 1) Full pilot (expand to additional 2 NC sites, then 3 VA sites)--target enrollment= 300 per site, 500 total for samples

## Data Collection

- Electronically administered biweekly questionnaire collecting the following data elements: demographics (baseline only), symptoms, and healthcare visits, adherence to mitigation recommendations (baseline and every 2 weeks).
- Mailed self-collected sample collection kit at biweekly intervals to a random sub-sample of study participants
  - Respiratory and blood samples

# Current COVID-19 Cohort Efforts - RECOVER Team

## VA Team

- Chris Hostler, MD (PI)
  - Chris Woods, MD (Co-I)
  - Maria Joyce, MD (Co-I)
  - Brad Nicholson, PhD (Co-I)
- 
- Cooperative Studies Program Epidemiology Center (CSPEC) Durham
  - Molecular Epidemiology Research Lab (MERL)

## Key Partners

- Duke-MURDOCK
- State of NC Lab



# Current COVID-19 Cohort Efforts-VA Epidemiologic Cohort of Veterans and Infectious Disease (EPICCOVID) - A CSP/MVP Partnership

- A population-based cohort and biorepository based on:
  - a random sample of Veterans representative of the VA population and their immediate households, selected through a state-of-the-art sampling design
  - all COVID-19 confirmed cases (tested or treated)
  - prospective longitudinal survey data and biospecimen collection
  - retrospective linkage to electronic medical records
- A comprehensive VA “learning healthcare system” model for COVID-19 clinical and research integration
- A rapid-response and scalable platform for potential future pandemics able to track other health conditions, both acute and chronic
- A VA-wide resource through integration with other infectious disease cohorts

# Current COVID-19 Cohort Efforts - EPICOVID

## Program Aims

- Produce generalizable knowledge regarding the epidemiology of infectious diseases within a nationally-representative sample of Veterans, focusing initially on SARS-CoV-2/COVID-19
- Provide the infrastructure for adapting to the fast-paced nature of a research response to an evolving infectious disease outbreak/epidemic/pandemic, using the current COVID-19 response as a model
- Integrate with ORD activities to establish a VA-wide biorepository of specimens from a population-based cohort of Veterans that can be used to address future research questions, including those related to SARS-CoV-2, as well as other infectious and non-infectious diseases of import to Veterans.
- Create a scalable integrated clinical-research tool for public health conditions affecting Veterans and VHA high priority disorders.

# Current COVID-19 Cohort Efforts - EPICOID

## Multiphased Approach

- Establish the EHR-based cohort
  - include all COVID-19 confirmed cases identified by the VHA (tested or treated)
  - design probability sampling selection scheme on all active VHA Veteran users
  - create and maintain mailing master list
- Questionnaire design and mailings
  - CSP Epi Program first case mailings, while contracts are being worked out
  - 2 invitational mailings; quarterly follow-up mailings
- Biospecimen collection
  - venipuncture at baseline; mail-in kits quarterly after
- Household cohort of Veterans' family members
  - address regulatory issues, family member questionnaire and biospecimen collection
  - Current Status-Awaiting ORD programmatic review

# Current COVID-19 Cohort Efforts - EPICOVID

1. Chair - Coordinating Center organizational infrastructure
2. Executive Committee:
  - under the VA ORD leadership,
  - with input from ORD Services, VA Field Offices, Veteran organizations, other stakeholders
3. Extensive knowledge-base and experience in terms of:
  - participant outreach and recruitment (e.g. phone interviews, travel teams, etc.)
  - survey design and large scale survey mailings
  - web-based questionnaire and consent form completion
  - data and biospecimen collection and banking
4. Scientific culture: clinicians, epidemiologists, statisticians, informatics scientists, etc.
5. Current Status: Awaiting ORD review

# Current COVID-19 Cohort Efforts - EPICOVID Team

- Mihaela Aslan, Co-Chair (CSP)
- Kelly Cho, Co-Chair (MVP)
- Jonathan Sugimoto, Co-Chair (Epidemiology)
- Craig Gunderson, Co-Chair (Clinical)
- Dawn Provenzale, Durham CSPEC Coordinating Center Director
- J. Michael Gaziano, MVP PI and Boston CSPEC Coordinating Center Director
- Nicholas L. Smith, Seattle CSPEC Director

**Special Acknowledgements:** Crystal Stafford, Stacey Whitbourne, Christina Williams, William Lance, Kellie Sims, Chris Woods, Jimmy Efir, Teresa Day

# Current COVID-19 Cohort Efforts - VA Cooperative Studies Program Research

CSP Epidemiology Studies - A Collaborative Multicenter Research Approach to COVID-19 infection

RECOVER will develop and test  
critical clinical processes for  
EPICOVID

Sampling frame

Questionnaire-mailing,  
tracking, online platform

Specimen self-collection,  
mailing, tracking, storing,  
return of results

Repository development

EPICOVID is  
Complementary to CSP 2028

Will collect similar data and  
biospecimens from a different  
sample of the VHA user  
population.

Will inform specimen and data  
collection of outpatients in  
CSP 2028 and as Veterans  
transition from the inpatient to  
the outpatient setting.

EPICOVID is Complementary to MVP

Will test similar processes in a  
population-based sample.

MVP to test recontact process  
for those who have enrolled,  
donated a blood sample and  
agreed to be re-contacted for  
additional research.