

Ambition to Grow Programs through Collaborative Research

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U.S. Department
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Presenter (Yorek) Disclosure

Consultant for Novo Nordisk and NeuroPn Therapeutics
(not relevant to this presentation)

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Points to Consider/Discuss for Growing your Research Program

- Get to Know your Affiliate and for them to Know You. Meet semi annually with College and Department Leaders.
- Offer to give presentations describing VA Research and Opportunities.
- Have a Vision, where would you like to see your VA Research Program next year, in five and ten years.
- Build from your Strengths. What do you do well and how can this be expanded?
- Recruit both MDs and non-physicians to your program. Meet individually with interested investigators. Explain the VA granting process. We are not NIH.
- Get to know your Service Line Chiefs. Get their input on how to expand Research at your VA.

Points to Consider/Discuss for Growing your Research Program (cont.)

- Establish a good working relationship with your Chief of Staff and Director. Share your Vision and get their input.
- Seek their support. Perhaps, by creating flexibility in FTE access or hiring a study coordinator assigned to the Research Office to help get human studies initiated and file IRB applications at your VA. Some affiliate investigators are reluctant to work with the VA believing there are too many obstacles and regulations. It will take some Education on your part to negate this misunderstanding.
- If you have a non-profit organization. Get to know the Executive Director and work to create collaborations with Private Industry. Perhaps hold joint meeting with site investigators and your non-profit organization so they all get to know each other.

Collaborating with other VAs

- The Cooperative Studies and Partnered Research Programs (PRP) are growing and providing more opportunities. Further details on PRP will follow later in this session. For more information on proposing or joining CSP studies, or their ACCESS Program for mentoring/training new sites, visit:
 - www.vacsp.research.va.gov
 - Or contact Marcus Johnson, marcus.johnson4@va.gov
- Also, VA Central IRB, the development of the Community IRB and recognition of more Central IRBs will help all VAs get involved in research especially if collaborating with another VA.
- Central Office ORD has expressed interest in supporting/encouraging smaller VAs without a current research program to work with a larger VA to create a program with assistance as needed from the larger VA.
- Guidelines were created to assist development of such partnerships.

Initiating or Re-Starting a Research Program

First Step: Is this going to be an Independent or Reliant Site?

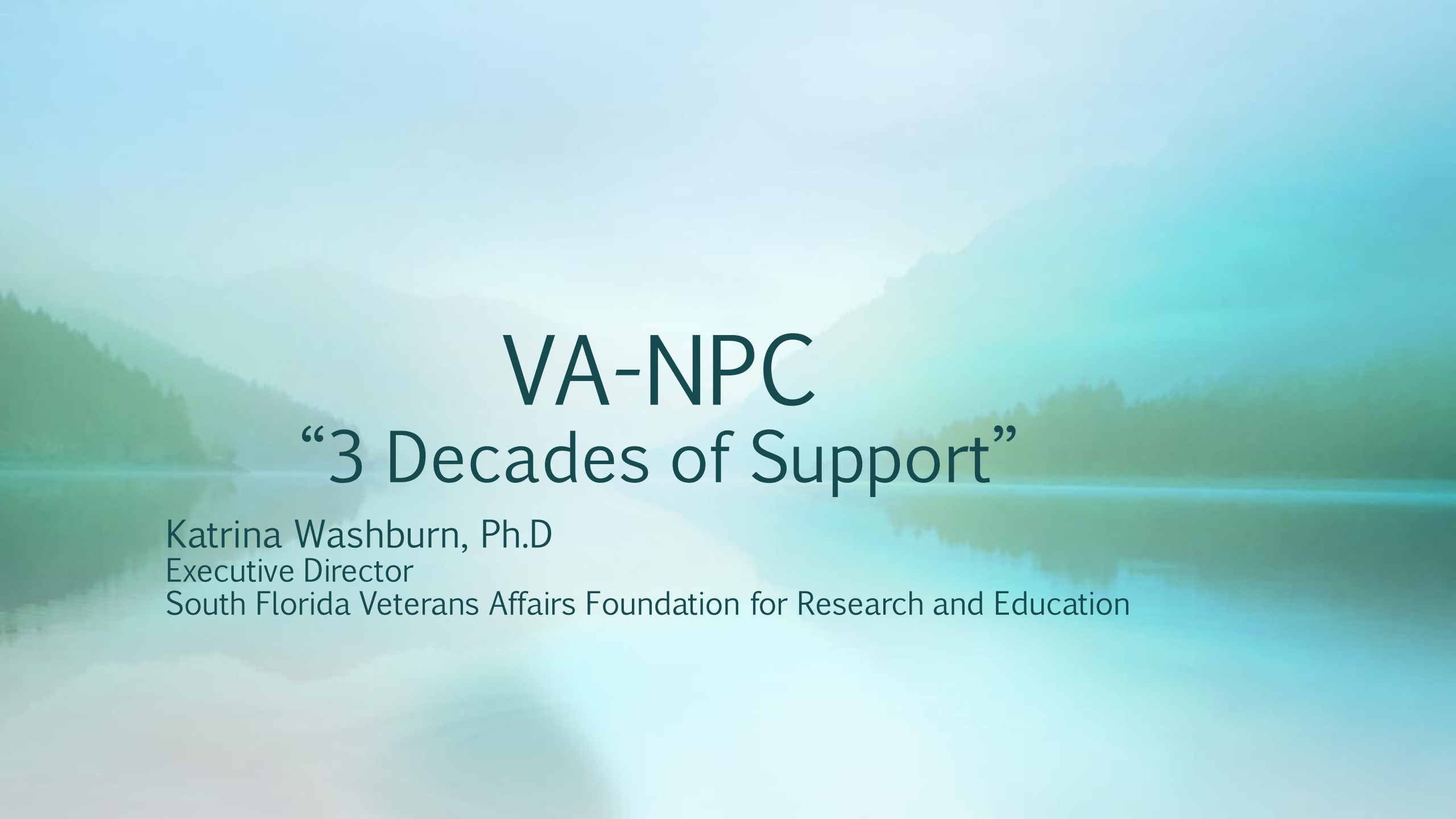
Second Step: Complete the application for the initiation or re-activation of a research program.

Points to Consider:

- a) Identify point person that will coordinate with ORD
- b) Determine the number of investigators and types of research
- c) Sustainable funding: How will the program be supported for the first 5 years
- d) Complete an Organization Chart identifying Research Service per 1200.02
- e) What is your hiring plan for Research Leadership and support staff (privacy, information security, safety, R&D committee etc.)
- f) VAIRRS implementation and training for staff and investigators
- h) How will you incorporate the Pharmacy to support Research activities if needed?
- i) How and what space, storage and equipment will be allocated to support R&D activities.
- j) Use of a Nonprofit? Will you share or create a new one?
- k) Do you have an affiliate and how will it support your research program?

Additional Steps:

- 1) Create MOUs if you are going to rely on a supportive site (another VA). What services/committees will you use from the supportive site?
- 2) If you are going to be an independent facility you will need to develop SOPs in the following areas: (responsibilities, communication, non-compliance reporting, education, R&D committee, IRBs, IACUC etc.)
- 3) Develop and RCO Plan
- 4) Indicate appointments by the Facility Director for your different committees and IRB
- 5) During this time, you and/or your supportive site will be working with ORO/ORD to review SOPs and MOUs
- 6) The goal will be to get local approval of SOPs and MOUs finalized
- 7) Eventually ORD sends Letter activating program



VA-NPC

“3 Decades of Support”

Katrina Washburn, Ph.D

Executive Director

South Florida Veterans Affairs Foundation for Research and Education

Build a strong relationship with your VA-NPC

- 1) Frequent meetings – virtual or in-person - between the VA Research Leadership (ACOS/R and AO/R) and VA-NPC staff are beneficial in developing programs and addressing challenges such as staffing, shared resources, and study management
- 2) Principal Investigators are encouraged to meet with the VA-NPC leadership to learn about new study opportunities and other ways the VA-NPC can help to support their research and education endeavors.
- 3) It is beneficial to invite the VA-NPC ED to the R&D Committee meetings in order to facilitate understanding and resolution of on-going program issues.
- 4) Lunch & Learns are a good way to hold large informative meetings – such as introducing a VA-NPC to a small VA research facility.
- 5) Small research programs can gain insight and support through discussing successes and challenges with the VA-NPC. Your VA-NPC can share lessons learned and may have resources to help further immediate goals. Also, the medical center director sits on NPC's Board and the ED has a direct line of communication to them.

VA-NPC MANAGEMENT OF FUNDS

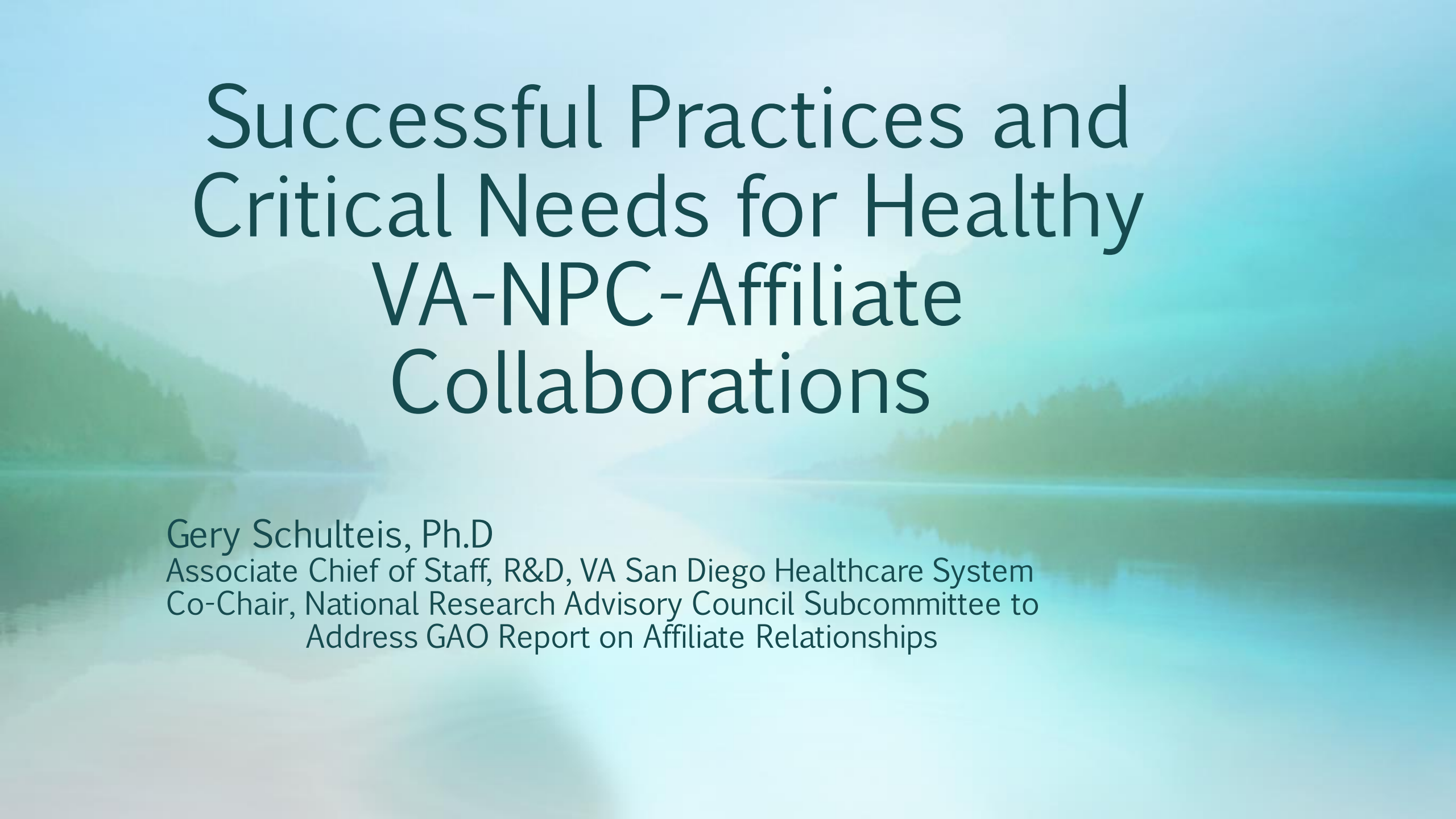
- 1) VA-NPCs are an excellent resource to help educate your PIs on applying for various types of non-VA funding such as federal awards (NIH, DOD, CDC, etc.), industry-sponsored clinical trial and private foundation awards.
- 2) VA-NPCs may have residual funds that can be requested through the Board to help assist small research programs. “Asks” could be for supplies, equipment, or support of research coordinators.
- 3) VA-NPCs have often been asked to work with Fiscal Service on managing research fundings including IPA agreements and Bill of Collections.
- 4) Although it’s not the primary mission of the VA-NPCs, they can fundraise to support small research programs.

Networking through your VA-NPC

- 1) NPC are worth they weigh in gold when it comes to networking.
- 2) NPCs are connected to various pipelines of funding opportunities. NPCs assist PIs in locating funded research and educational opportunities through industry-partners, federal research & educational funding announcements, and private foundations.
- 3) A multi-site NPC can make introductions between physician-scientists at the VAs they service, which builds collaborations.
- 4) Example: At one of the NAVREF's Industry-Partnership Consortium Meeting, I was fortunate enough to meet representatives from Mirati Therapeutics, Inc. and GRAIL, LLC. From this meeting, I brought their clinical trials to the Miami VA LPOP group, and they were interested. Being a multi-site VA-NPC serving Miami VAMC, Orlando VAMC and West Palm Beach VAMC, I was able to connect physician-scientists at these facilities with the Miami VAMC LOP group. These physician-scientist joined the LPOP meetings, learned about the trials, and began collaborations. We are now in the process of starting the Grail study at West Palm Beach.

Hiring Practices

- 1) The NPC can be a great resource and assistance in hiring staff.
- 2) **New Physician-Scientist:** It is a best practice to include the VA-NPC ED in the hiring process of new Physician-Scientists. It helps to attract experienced Physician-Scientists to a facility with a small program. The VA-NPC can highlight benefits offered, such as: fund management, residual fund policies, pipelines to clinical trials, help with hiring staff, faster ordering of equipment and supplies, etc...
- 3) **New VA Research Staff:** Hiring VA research staff can take a long time depending on your facilities processes. Most people don't want to wait 6 to 9 months to be hired. The NPCs can hire in a very short time, providing the person has the WOC appointment. If using VA funds to support a position in the NPC, the person can be placed on an IPA agreement after 90 days of employment by the NPC.
- 4) Example: if the small research program has been awarded a CSP and needs to hire staff, it may be possible to ask the VA-NPC to hire them and support them for 90 days. After which, they can be supported by the CSP funds through the IPA mechanism.



Successful Practices and Critical Needs for Healthy VA-NPC-Affiliate Collaborations

Gery Schulteis, Ph.D

Associate Chief of Staff, R&D, VA San Diego Healthcare System
Co-Chair, National Research Advisory Council Subcommittee to
Address GAO Report on Affiliate Relationships

Successful Practice: Ensuring Understanding of the Overall Partnership

Summary: Sites with successful partnerships typically share a common understanding of the full Academic Affiliate/VA relationship (i.e., including shared faculty, educational programs, clinical programs, research in context of the overall shared missions).

- Viewing research in isolation can lead to assumptions of the VA, NPC and Affiliate as “competing” for grant applications, rather than key contributors to a partnership where everyone gains, sometimes to varying degrees in different dimensions (excellence in clinical care, effective training programs, joint faculty recruitment, research opportunities).
- Even within just the research domain itself, there are opportunities for synergistic relationships, for example utilizing each other’s core services, sharing of research staff with critical and specialized expertise, and joint applications for research funding where the multiple partners’ combined capabilities make for stronger applications
- Joint-Appointed/Recruited PIs who are invested in the shared missions of all partners is a key hallmark of success.

Successful Practice: Communication Mechanisms

Summary: Strong communication practices among VA, NPCs, and VA Academic Affiliates are critical to foster effective partnerships.

- VAMC leadership should lead efforts to integrate the NPC partner into discussions in collaborative endeavors
- Establish routine communication practices across the three entities to incorporate regular meetings and foster the free flow of information
- Implement a system for reciprocal communication on pending grant applications that involve the resources of a partner
- Educate investigators and departmental grants administrators on the policies or agreements in place governing where extramural funding is administered

Successful Practice: Written Agreements

Summary: Establish clear, well defined, transparent, formalized agreements among the local partners regarding extramural awards administration, shared resources (e.g., cores), and other partnership agreements as appropriate.

- Research Affiliation/Collaboration Agreements (ORD may wish to consider development of a template similar to OAA agreements)
- Elements of Partnership Deserving of Consideration for Written Agreements:
 - Sharing of space/equipment/core facilities
 - Dual appointment policies and procedures
 - Communication on compliance issues that may affect other partners
 - Mechanisms for appropriate administration of extramural awards
 - Common successful examples include “preponderance rules” and routine subawards between partner sites

Critical Need: Personnel Development

Summary: Provide (at Central Level, e.g., ORD, NAVREF) and leverage (individual sites) mentorship/ development programs for ACOS R&D, NPC Executive Directors, with focus on affiliate partnership best practices.

- ORD has an ACOS/AO Mentorship Program for those NEW to their roles; this should be expanded to allow for mentorship specifically in the area of effective VA/NPC/Affiliate partnerships, even for established ACOS/R&D at sites with limited partnerships at present.
- The NAVREF Executive Director Mentorship Program should be similarly expanded to provide training in effective partnership development.
- The “Toolkit” product of this NRAC Subcommittee is envisioned to be an ever-expanding online resource of guidance documents, best practice examples, agreement templates, etc., that will be maintained on the ORD Internet site, but also available to NPCs through NAVREF.
- Support joint VA/NPC/academic affiliate recruitment to build the critical stakeholder base of Principal Investigators with a stake in the shared missions

Critical Need: NPC Development to Serve as a Critical Partner

Summary: Strategic planning of NPC infrastructure growth to effectively service investigators with awards of varying types/scopes/size; effectively marketing the organization and its capabilities as an administrator of extramural awards to the VA Principal Investigator community. Success in this arena may be gradual, and involves:

- Strengthening of NPC Governance Activities, to include Board education in advantages to partnership
- Developing and Maintaining Excellent NPC Business Operations that can provide a level of service to investigators that equals that of the affiliate
- Improve Awareness of NPCs Through Outreach

Critical Need: VHA/ORD Action Items

- **Summary:** Enhance communication among and provide guidance (via online Toolkit) to all stakeholders in areas identified by focus groups as significant challenges to effective partnership.
- Establish national enterprise-level communication with Affiliates and the NPC community, coordinating such efforts with NAVREF and AAMC
- Develop a Research Affiliation Agreement Template
- Authorize and promote the establishment of research relationships with entities other than the site's primary educational affiliate
- Communicate guidelines and practices to the field to remove perceptions of obstacles to collaboration
- Establish and maintain an ORD toolkit repository for successful research partnership practices, documents and templates



VA's Partnered Research Program

Krissa Caroff, MS
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Partnered Research Program, Office of Research &
Development

History: Access to Clinical Trials For Veterans

- Launched April 2018 – 2-year initial effort to facilitate partnerships with external entities
 - Collaboration between ORD, NAVREF and multiple stakeholder groups from VA, industry and patient groups
- Emphases:
 - Facilitating interactions and trial start-up process with VA in an enterprise approach
 - Highlight VA experiences, resources and leadership
 - Bring Veterans more opportunities to novel therapies and opportunities

PARTNERED RESEARCH PROGRAM

- Launched March 2020 (accelerated by COVID-19 pandemic)
- Serves as the initial point of contact (“Front Door”) for external organizations interested in partnering with VA on industry sponsored multisite clinical trials.
- Priorities
 - Establishing and enhancing partnerships for long-term benefit
 - Connecting clinical research groups with VA resources/stakeholders
 - Navigation of VA clinical research enterprise
 - Continuous improvement
 - Study start up activities
 - Identifying challenges and best practices
 - Collaboration mechanisms



What Services Are Available via the PRP?

The following general services are available to any external organization:

- Provide information and guidance related to partnering with VA on multisite clinical trials
- Communicate upcoming or ongoing awarded trial opportunities seeking VA sites/investigators for which an urgent response (i.e., less than 10 business days) is not required.
- Facilitate connection between organization and VA clinical and scientific experts.
- Facilitation of centrally executed Confidentiality Disclosure Agreements (CDA) for any trial for which 3 or more VA sites have expressed interest
- Facilitation of Master Agreements (e.g., Master CDAs and Cooperative Research and Development Agreements (CRADA))

PRP helps make connections and starts groups on the path for successful partnership

What PRP Does Not Do

The Partnered Research Program does not serve as a Site Management Organization.

VA facilities are still responsible for all aspects of their respective start up. PRP serves as a resource & guide.

Sponsor (or their CRO) will work directly with VA sites re:

- Site feasibility
- Pre-Selection visits/questionnaires, etc.
- Required reg documents, IRB submissions, local reviews and approvals, training, etc.
- CRADA and budget

PRP is not a replacement for the responsibilities of sponsors, investigators or facilities.

https://www.research.va.gov/programs/partnered_research/

The screenshot shows the VA Office of Research & Development website. The header includes the VA logo, the U.S. Department of Veterans Affairs name, and search/contact options. The main navigation bar contains links for Veterans Benefits and Health Care, About VA, and Find a VA Location. The breadcrumb trail indicates the current page is the VA Partnered Research Program. The page title is "Office of Research & Development". A sidebar on the left lists various programs, with "ORD Programs" expanded to show "See All Programs", "Animal Research", "Biosafety & Biosecurity", and "Centralized Interactive Phenomics". The main content area is titled "VA Partnered Research Program" and includes an "Overview" section. A red arrow points to a link titled "Request for Collaboration by External Organization".

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VA Partnered Research Program

Overview

The Partnered Research Program (PRP), established in March 2020, is a division of the VA Office of Research and Development dedicated to developing partnerships to enhance Veterans' access to high quality, multisite clinical trials. PRP's overall goal is to establish long-term relationships with external organizations that are committed to Veterans' health and VA's clinical research mission. These activities are intended to build on VA's long-standing history and leadership in multi-site clinical studies aimed at impacting clinical practice and health for Veterans and the nation.

Key PRP activities include:

[Request for Collaboration by External Organization](#)

Key Considerations/Takeaways

- PRP's primary role is to guide stakeholders involved in industry sponsored multisite clinical trials.
 - We do this through the identification and implementation of tools, SOPs, work aids, etc., which standardize and streamline trial related activities. Examples:
 - Centrally Executed CDAs
 - Preferred single entry point for industry sponsors (EARLY engagement is highly recommended)
- Efforts are designed to engage the key stakeholders at the site level: Research Office leadership, VA affiliated NPCs and Research Team.
- We are not seeking to change HOW your local facility processes work, but we are trying to ensure that study sponsors and CROs understand how the heterogeneity may impact their start up timelines and are prepared appropriately.
- We are NOT a Site Management Organization
- We do not replace the functions of the CRO

Contacts

Webpage:

https://www.research.va.gov/programs/partnered_research/

Email: VAPartneredResearch@va.gov