



VA Innovation and Research Review System (VAIRRS)

Monthly Webinar

August 23, 2022



Webinar Housekeeping



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 - **Please do not use Chat to send in questions**
 - **Be sure to send questions to "all panelists"**
- Complete the post-webinar evaluation survey that pops up once you exit the webinar.
- Experiencing sound issues? You can call in using the number included on the handouts and on your registration confirmation email.

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Multiple Co-Principal Investigators at Different VA Facilities



Important Announcements



VAIRRS Strategic Plan and New Webpages

The VAIRRS FY 2022 – 2024 Strategic Plan is now available to the public and is located on the VAIRRS website. Also, we updated and added new VAIRRS webpages in effort to benefit the end-user experience.

Dashboard Updates

A new page has been added to the field dashboards that reflects study team training data. Please review the new page and submit all feedback to VAIRRSDashboards@va.gov.

VAIRRS Mentor Program

As we move into our third year, we are planning a major update to the mentor program. We will soon be able to offer paid (yes, PAID!) opportunities to serve as a VAIRRS Mentor.

*Subscribe to the **VAIRRS Newsletter and Program Update** to keep up with important announcements and program updates: https://public.govdelivery.com/accounts/USVHA/subscriber/new?topic_id=USVHA_1952*



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VA Central IRB Submission Process: Multiple Co-Principal Investigators at Different VA Facilities



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Objectives

The VA Central IRB (CIRB) will outline a new submission process for when a Principal Investigator/Study Chair (PISC) New Project has multiple Co-Principal Investigators (PIs) **located at different VA facilities.**

If all Co-PIs are located at the same VA facility, the submission process outlined in this webinar should **NOT** be followed.

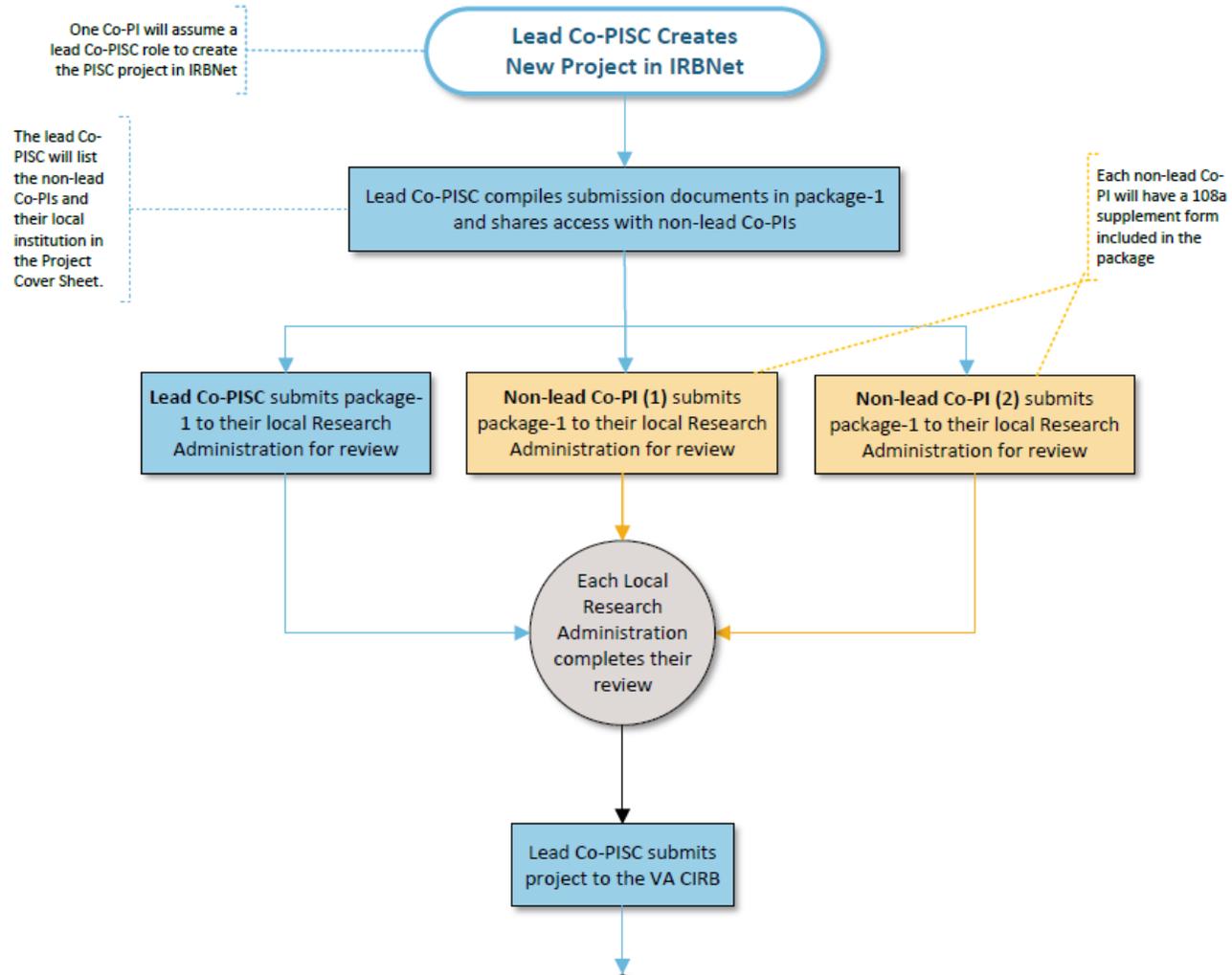


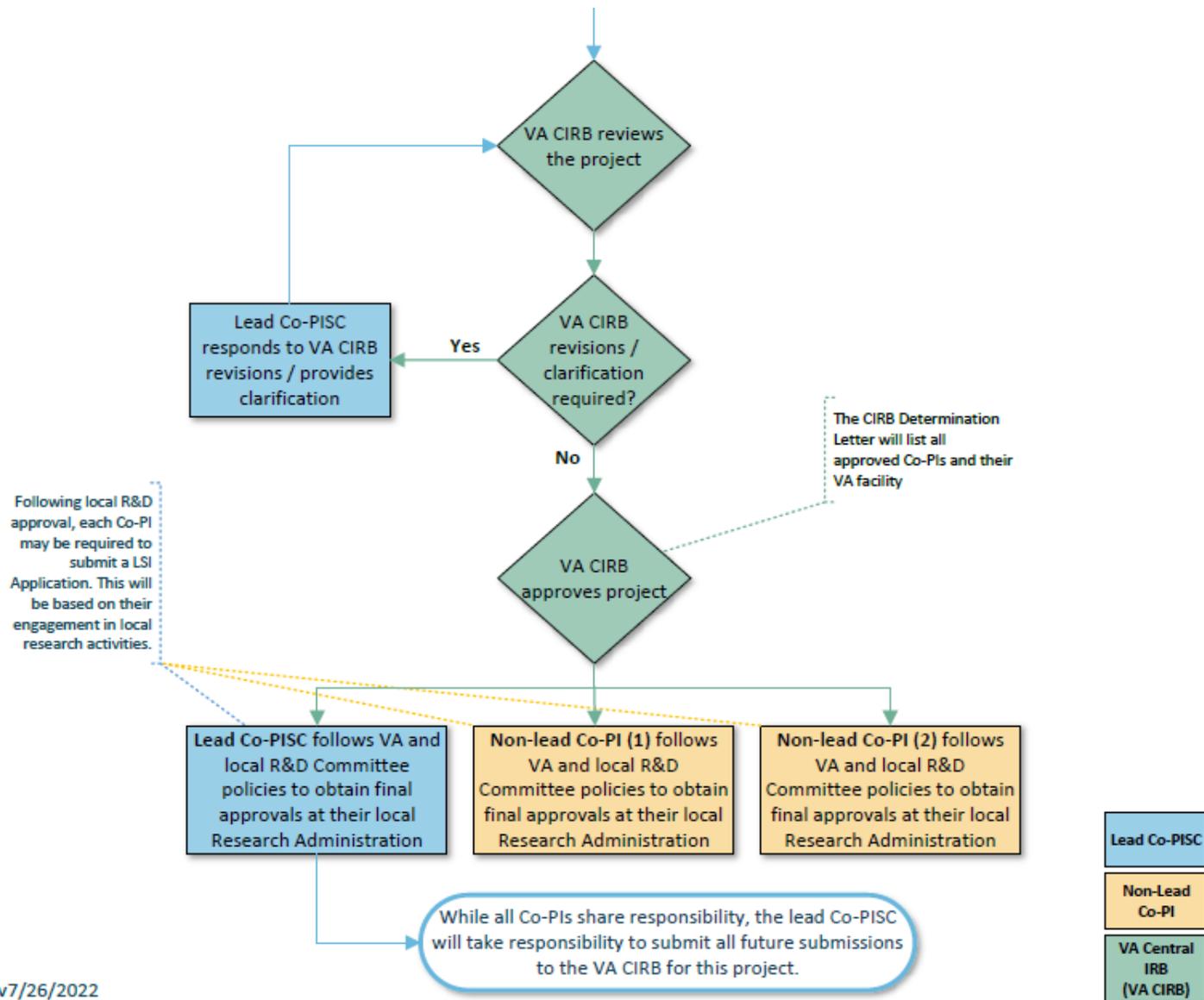
Definitions

- **Principal Investigator/Study Chair (PISC):** The PISC is the investigator with responsibility over the entire project. The PISC oversees scientific, technical, and day-to-day management of the research conducted across engaged and non-engaged local sites. PISC also refers to the application process for getting VA CIRB approval.
- **Local Site Investigator (LSI):** The LSI is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research conducted at the local site. The LSI also refers to the application process for getting CIRB approval for the investigator and the site where the study will be conducted, which is linked to the PISC application, but distinct from it.
- **Co-Principal Investigator (Co-PI):** A Co-Principal Investigator is an individual who shares equal oversight and responsibility with the other Co-PI(s) for the conduct of a research project all of which is detailed in the above PISC definition.
- **Lead Co-Principal Investigator:** For purposes of IRBNet only, one of the Co-PIs must assume the lead Co-PI role. The lead Co-PI will be responsible for creating the project in IRBNet, sharing it with the non-lead Co-PI(s), and make all required submissions to the CIRB. The lead Co-PI will be the named recipient for all CIRB notifications and communications for the project.

VA Central IRB

New Project Submission with Co-PIs Located at Different VA Facilities





Important Notes

- When Co-PIs are located at different VA facilities, one of the Co-PIs will need to assume a lead role.
- IRBNet only allows for one lead Co-PI in the system, regardless if there are multiple Co-PIs.
- The lead Co-PI will take responsibility for submitting the PISC New Project Application to the CIRB.
- All Co-PIs (lead and non-lead) must submit the PISC Project to each of their local Research Administrations prior to submitting to the CIRB. This will ensure local oversight of each Investigator's involvement on the project.
- The CIRB cannot describe the review process that occurs at the local Research Administration as each site's process varies. Please contact your local Research Administration or Local Site Liaison for specific instructions.

Example

- There are three Co-PIs on a PISC New Project Application.
- One is located at Atlanta VAMC, one at Boston VAMC, and one at Cincinnati VAMC.
- All three Co-PIs have equal responsibility and oversight of the project.
- In this example, all three Co-PIs will follow these instructions when creating and submitting the project in IRBNet.



Step 1

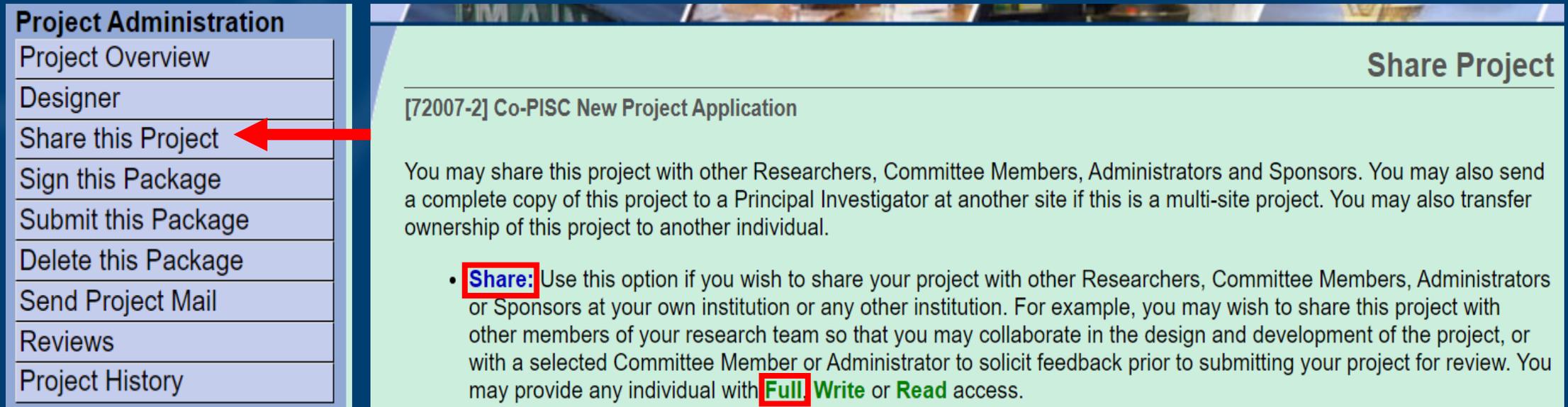
One of the 3 Co-PIs will need to assume the lead role for this project.

The lead Co-PI will create the PISC New Project in IRBNet and compile all applicable submission forms according to our standard process outlined in the CIRB guidance document titled *INSTRUCTIONS - PI and LSI New Project Submission*.

- **Form 108a Co-PISC New Project Application Supplement** must be completed for each of the non-lead Co-PIs and be included in the New Project package.
- **Project Cover Sheet Wizard** must list each Co-PI and their primary VA location.

Step 2

The lead Co-PI will “Share this Project” with each non-lead Co-PI and assign each of them full access to the project.



The image shows a screenshot of a web application interface. On the left is a vertical menu titled "Project Administration" with the following items: Project Overview, Designer, Share this Project, Sign this Package, Submit this Package, Delete this Package, Send Project Mail, Reviews, and Project History. A red arrow points to the "Share this Project" option. The main content area is titled "Share Project" and contains the following text:

[72007-2] Co-PISC New Project Application

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.



Step 3

The lead and non-lead Co-PIs will simultaneously submit the project (i.e., package -1) to each of their local Research Administrations.

***NOTE:** A single package can be submitted to more than one board. In this instance, all Co-PIs can submit the same package to each of their local Research Administrations for review (see figure to the right).

Welcome to IRBNet
Lindsey Researcher

Help

My Projects

Create New Project

My Reminders (264)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Reviews

Project History

Create a New Package

Messages & Alerts (2)

Other Tools

Forms and Templates

Submit Package

[72007-2] Co-PISC New Project Application

IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

This document package has been submitted to:

- Cincinnati VAMC Research Administration, Cincinnati, OH
- Atlanta VA Health Care System Research Administration, Atlanta, GA
- Boston VA Health Care System Research Administration, Boston, MA

Please select a Board:

Search for an Organization | VA | Search | Clear

Only show My Default Boards

Select a Board *

- Air Force Headquarters, Falls Church, VA
- Aleda E. Lutz VAMC Research Administration, Saginaw, MI
- Arkham VAMC Research Administration, Arkham, MA
- Asheville Charles George VAMC Research Administration, Asheville, NC
- Bay Pines VA Health Care System Research Administration, Bay Pines, FL
- Belvedere VAMC Research Administration, Belvedere, OH
- Birmingham VAMC Research Administration, Birmingham, AL
- Boise VAMC Research Administration, Boise, ID

Continue | Cancel

* required fields



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Step 3 cont.

When the lead and non-lead Co-PIs submit the package to their local Research Administrations, they need to include in the comments section that it is a project with Co-PIs located at different VA facilities, with the lead Co-PI being listed as the Principal Investigator in IRBNet and on the submission forms.

This is important for non-lead Co-PIs, as their information will not be listed as Principal Investigator when they submit to their local Research Administration. Non-lead Co-PIs can direct their local research administrations to review the Form 108a and Project Cover Sheet (PCS) where they are listed as Co-PIs.

Submit Package

[72007-2] Co-PISC New Project Application

The following users at **Durham VAMC Research Administration** will be automatically notified of your submission:

- Aldridge, Marion
- Christian, Kenan
- Crew, Ida
- Green, Brendlin
- Jones, Kathi
- Komoski, Stephanie
- Taylor, Courtney

Submission Type: *

You may also specify additional comments to be included in this notification.

Your Comments:

This is a multi-site PISC New Project that is being submitted for local review before it goes to the VA Central IRB for review.

Please note that this project has 3 Co-PIs all located at different facilities. My role on this project is a non-lead Co-PI. Dr. Jones will be the lead Co-PI on this project therefore his name is listed as Principal Investigator in IRBNet and on all submission materials.

Thank You,
Dr. Smith



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Step 4

- Each local Research Administration will complete their local review (i.e., COI Determination, ACOS signoff on Form 102, etc.)
 - A Form 102 with ACOS signoff for each Co-PI (lead and non-lead) must be uploaded into the package that is submitted to the CIRB.
- *NOTE:** This step allows local Research Administrations to have awareness and oversight of the Co-PIs role in the project.

Step 5

- After all local Research Administration reviews are complete, the lead Co-PI will submit the project to the CIRB.
- The package that is submitted to the CIRB should only include documents that are required by the CIRB. Do not include local forms.



Step 6

- The CIRB will review the new project.
- During the CIRB administrative review process revisions, clarification, or other requests may be made prior to the submission receiving CIRB review.
- This process will occur utilizing IRBNet’s “Unlock and Lock” function so that you can add, remove, or revise documents within the same package.



Step 7

- After final CIRB approval is received, each Co-PI will follow their local R&D Committee policies to obtain final approvals at their local Research Administration.



Additional Considerations

- **Will the Co-PIs have to submit an LSI application after final R&D Committee approval of the new project?**

Following local R&D Committee approval, each Co-PI may be required to submit an LSI application to the CIRB. This is the same as with any PISC project and will be based on the Co-PIs engagement in local research activities.

Our standard process outlined in the CIRB guidance document titled *“INSTRUCTIONS - PI and LSI New Project Submission”* should be followed if an LSI application needs to be submitted.

If there is uncertainty on whether an LSI application needs to be submitted for a Co-PI, then please consult with the CIRB manager overseeing the project.

Additional Considerations

- **Will all Co-PIs be named as Principal Investigators in IRBNet and on CIRB determination letters for the project?**

IRBNet only allows for a single Principal Investigator to be listed on a project and in order to support this process, the Investigator to be named will be the lead Co-PI. Currently, there is no capability to name Co-PIs within IRBNet.

As a result, the lead Co-PI will be the named recipient on all CIRB determination letters and other official communication for the project. When necessary, the CIRB will document the name of each non-lead Co-PI and the name of their VA Facility within the body of the letter.

Additional Considerations

- **Who will be responsible for making future submissions to the CIRB?**

While all Co-PIs share equal oversight and responsibility, the lead Co-PI will submit all future submissions to the CIRB for this PISC project given the parameters within IRBNet.



Additional Considerations

- **Who will receive project notifications, for example project expiration notices?**

All Co-PIs will receive IRBNet notifications for the project because each of them will have been granted Full Access to the project.



Questions?



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Contact Information

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For general VAIRRS support, please contact VAIRRS@va.gov

