Strategic Plan

Fiscal Year 2022 – 2024

July 2022

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Introduction

The Department of Veterans Affairs (VA) has improved the lives of Veterans and all Americans through health care discovery and innovation for over 95 years.

VA is on the leading edge of research and innovation. VA researchers developed the first cardiac pacemaker, performed the first liver transplant, created the radioimmunoassay to diagnose numerous diseases, and have made significant advances in the treatment of hypertension, cardiac surgery, post-traumatic stress disorder, and most recently, in the treatment of COVID-19.

> [1] VA research seeks to increase Veterans' access to high-quality clinical trials; increase the real-world impact of VA research; put VA data to work for Veterans; actively promote diversity, equity and inclusion; and build community.

Safeguarding the rights and welfare of human subjects in research is of critical importance to VA and other health-related US agencies. For this reason, the Food and Drug Administration (FDA) requires an institutional review board (IRB) to review and monitor biomedical research involving human subjects. The IRB does this by evaluating whether the risks to humans are reasonable compared to the potential benefit that may result from the research. VA's Institutional Animal Care and Use Committee (IACUC) and Institutional Biosafety Committee are charged with ensuring the humane treatment of laboratory animals and safe laboratory procedures for research.

The Office of Research Protections, Policy, and Education (ORPP&E) operates within the Veterans Health Administration (VHA) Office of Research and Development (ORD). ORPP&E is responsible for policy development and guidance for human research protection in the VA, training and education in human research protection, and the oversight and administrative support of the VA Central IRB. The VA Innovation and Research Review System (VAIRRS), one of ORPP&E's flagship programs, was established in February 2020. VAIRRS assists VA research programs in the review, tracking and oversight of VA research.

VAIRRS offers several web-based solutions to help researchers and administrative offices manage research protocol submissions to regulatory oversight committees and track through the regulatory review process. VAIRRS is used by all VA medical centers (VMACs), and/or sites, with research programs. As of July 2022, 106 sites have implemented VAIRRS.

> **THE MISSION OF VA RESEARCH**
> - Improve Veterans' health and well-being via basic, translational and clinical health services, and rehabilitation research
> - Apply scientific knowledge to develop effective individualized care solutions for Veterans
> - Attract, train and retain the highest-caliber investigators, and nurture their development as leaders in their fields
> - Assure a culture of professionalism, collaboration and accountability, while maintaining the highest regard for research volunteers' safety and privacy

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[1] Ten Times VA Led the Way in Health Innovation, VAntage Point, July 2021
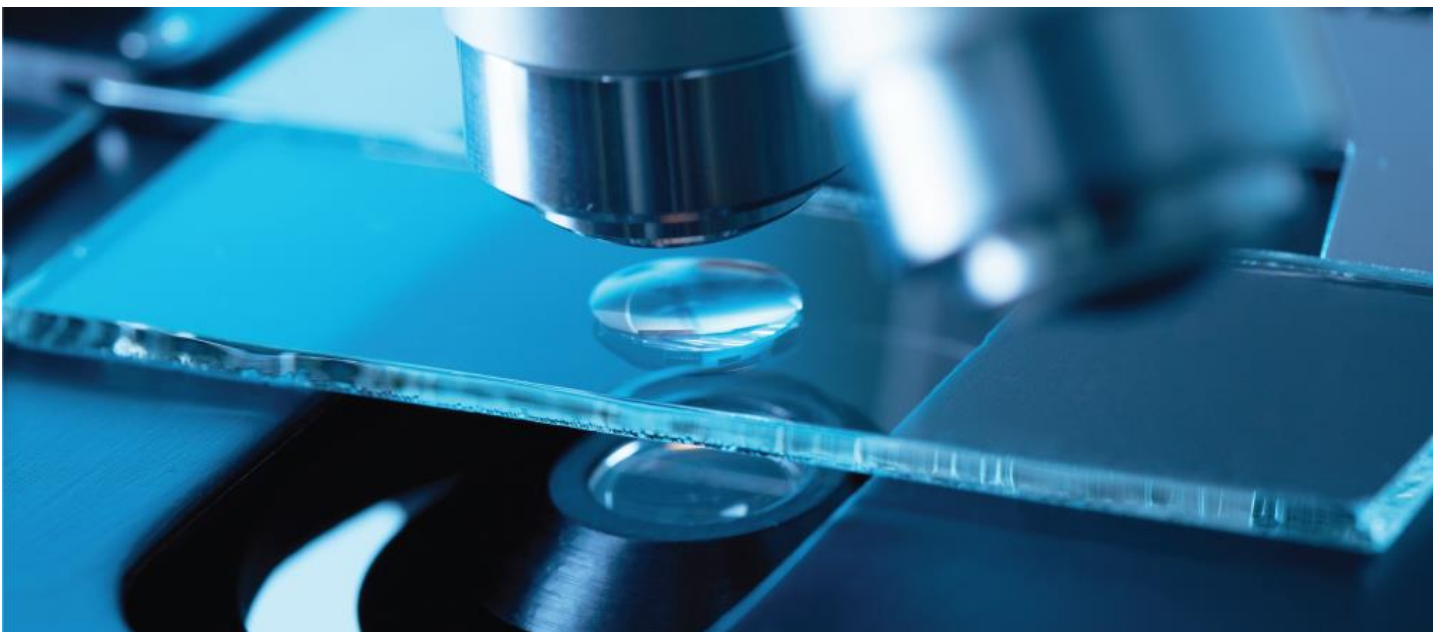
The Benefits of VAIRRS

VAIRRS is uniquely positioned to assist VA research programs in the review, tracking and oversight of VA research. The VAIRRS toolbox of capabilities assists in driving compliance and productivity for administrators, committee members, researchers and sponsors and can withstand the pressures of VA's research needs, including:

- Oversight needs of the research programs and institutions

- Collaborative needs of dually appointed VA investigators

- Regulatory changes of the new Common Rule (2018)

As of July 2022, VAIRRS has over 32,000 registered users, more than 298,000 packages and more than 600,000 documents submitted into the system. With VAIRRS, VA is moving toward a single source of truth for VA research, enabling user's access to the same system and information. This provides VA with consistent access to research data in real-time, making it easier for sites to collaborate and disseminate information. VAIRRS can accelerate the movement of research from bench to bedside, keeping VA at the forefront of medical research. Moreover, VAIRRS dashboards offer leaders important data visualizations for key decision making, enabling them to become more proactive in the management of research activities in their portfolio.

To support end-users, VAIRRS provides an extensive library of knowledge-based materials, baseline trainings, a support inbox, newsletters and program updates, webinars, and additional mechanisms to provide technical assistance and mentorship to sites in need. Once VAIRRS is integrated into a site's workflow, VAIRRS can support the improvement of processes and reduce the administrative burden related to research administration.
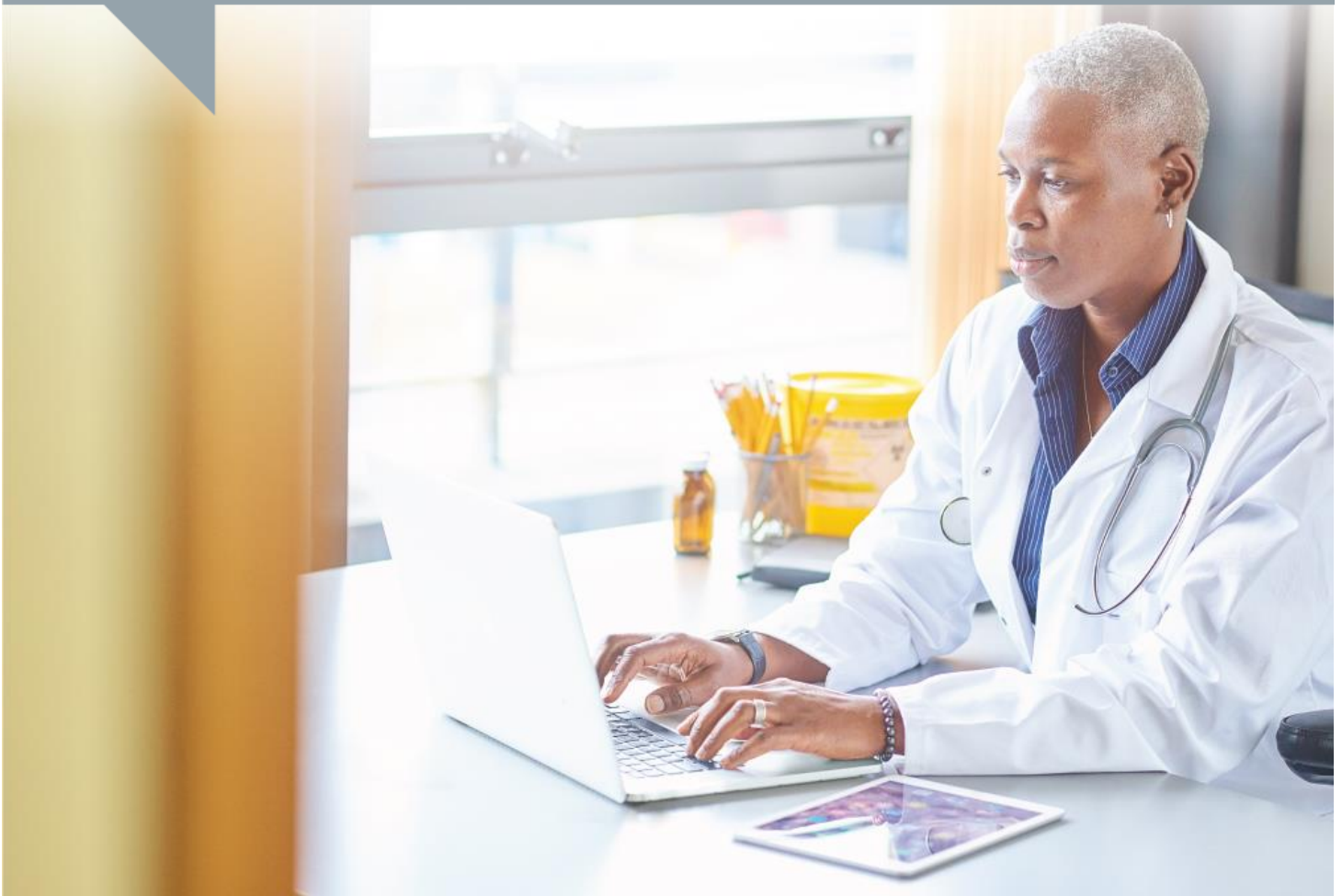
VAIRRS Mission:

The **VA Innovation and Research Review System (VAIRRS)** supports management of the research enterprise and processes of research-related stakeholders in VA.

VAIRRS Vision:

VAIRRS seeks to be the trusted review platform and data source for all research-related stakeholders.

VAIRRS Fiscal Year 2022 – 2024 Goals

Over the next two years, VAIRRS will continue its foundational mission of supporting research-related stakeholders while continually improving, evolving and promoting the additional value it offers VA researchers, administrators, technologists and leaders. To guide this path forward, VAIRRS has selected five programmatic goals that will frame activities from fiscal year (FY) 2022 to FY 2024.

1   Foster an **educated** and **self-reliant** stakeholder group

2   **Evolve** and **grow** the VAIRRS program to meet the needs of VAIRRS stakeholders

3   Continually **optimize** and **maximize** the use of VAIRRS

4   Provide local and enterprise leadership and other research-related stakeholders with a **decision support tool** driven by an **authoritative data source**

5   Promote the local and enterprise **value** and **uses** of VAIRRS

Figure 1. VAIRRS programmatic areas represented by goals.

VAIRRS Objectives and Key Performance Indicators

VAIRRS defined programmatic objectives for each goal. The program also identified key performance indicators (KPIs) aligned to the goals and objectives.

Strategic Goal 1:

Foster an educated and self-reliant stakeholder group

Goal 1 Objectives

- Maintain the VAIRRS Learning Library
- Develop role-based training curriculum maps
- Maintain Monthly Learning Calendar
- Maintain navigational guides
- Facilitate collection and dissemination of best practices
- Grow Mentor Program

Possible Goal 1 KPIs

- Publish role-based training maps by the end of Q1 FY23
- Increase number of best practices shared monthly
- Increase number of mentors and mentees enrolled in Mentor Program

VAIRRS' initial priority is to optimize training to foster an educated and self-reliant stakeholder group. Encouraging an educated stakeholder group paves the way for end-users to take ownership and maintain VAIRRS within their own research programs and builds the foundation necessary to achieve the long-term program vision of becoming the trusted platform and data source for all research-related stakeholders. An involved and collaborative end-user base will further solidify the accuracy and authority of VAIRRS data, shed light on additional opportunities for process improvement, and garner engagement from the field.

VAIRRS will promote an environment of self-education and independence through optimizing and maintaining the VAIRRS Learning Library on SharePoint to make it easier for end-users to locate training that meets their needs. The development of role-based curriculum maps will enable end-users to follow a customized training journey. Reference resources that directly relate to the user's role and responsibilities will also be available. VAIRRS plans to build and maintain navigational guides, which will help establish a library of readily available training resources that will aid end-users in completing technical tasks.

Regular maintenance of the VAIRRS Monthly Learning Calendar will continue to inform users of upcoming training opportunities offered within the program, which can supplement the baseline training. In addition, the creation of a mechanism to facilitate the collection and dissemination of best practices developed by users will foster an environment of cross-pollination and collaboration within the VA research community.

Strategic Goal 2:

Evolve and grow the VAIRRS program to further support VAIRRS stakeholders

Goal 2 Objectives

- Optimize and manage the VAIRRS SharePoint
- Manage VAIRRS inbox
- Improve the standardized library of forms and templates
- Develop a staffing model for VAIRRS
- Maintain strategic plan

Possible Goal 2 KPIs

- Increase number of active VAIRRS users
- Reduce VAIRRS support inbox response time
- Increase number of forms in ORPP&E library
- Publish VAIRRS small program staffing model in FY23

VAIRRS' operations ensures that the program evolves and grows internally to support leadership and the field.

VAIRRS will optimize the SharePoint portal, the main internal landing page for the program, to make it easier for end-users to navigate and locate information about training and education as well as additional resources. Continuous management of the VAIRRS support inbox will keep an open line of communication with the field. VAIRRS will enhance the inbox to serve the function of a help desk and provide quicker responses to end-users. Moreover, VAIRRS will regularly review and improve the standardized library of forms and templates. The program will develop new forms for other committees, as directed by the VAIRRS Change Control Board (CCB).

The development of a long-term staffing model will be critical to expanding VAIRRS capabilities. The new model will enable VAIRRS leadership to focus on the direction and evolution of the program and provide opportunities for additional support staff to collaborate on goals. Continuous maintenance and frequent review of initiatives and the strategic plan are vital to the overall program success.

Strategic Goal 3:

Continually optimize and maximize the use of VAIRRS

Goal 3 Objectives

- Establish VAIRRS Strategic Advisory Council (VSAC)

- Develop a mechanism to catalog feedback regarding VAIRRS functionality

- Determine feasibility of integrating ePROMIS into VAIRRS

- Provide site support

- Develop a repository of site profiles

- Expand VAIRRS data utilization across other VA programs

- Monitor accurate completion of wizards

Possible Goal 3 KPIs

- Increase adoption and use of VAIRRS data to actively manage operational and research activities

- Publish site profile index

- Publish site support entry/exit plan

Ensuring the effectiveness and utility of VAIRRS is paramount in the program's success. VAIRRS will continually identify opportunities to optimize the program as it grows. The first step in accomplishing this goal is the deployment of mechanisms to gather insights from the field, as their buy-in and execution of the program rely on a productive partnership. To that end, VAIRRS completed a series of site interviews, which elicited recommendations and constructive feedback from end-users to guide continuous improvement. VAIRRS established a site support department that has helped foster a positive rapport and proven to be a valuable resource to the field. To ensure further progression and improvement, site support will evolve and develop entry and exit criteria, helping to establish clear goals and expectations.

VAIRRS will establish the VAIRRS Strategic Advisory Council (VSAC) to ensure it is meeting the needs of end-users and that the impact of strategic initiatives is considered before implementation. In addition, VAIRRS will create site profiles, which will provide snapshots of specific sites within the field, including quantitative data from IRBNet, qualitative data from site interviews, interactions and survey responses. These new mechanisms will contribute to the continuous improvement of VAIRRS and support the development of new opportunities identified by internal ORD members.

The foundation of VAIRRS is rooted in obtaining accurate and complete data from the field. VAIRRS seeks to identify additional VA programs where synergies exist to combine data and leverage tools in a way that increases value for interested stakeholders. VAIRRS will develop initiatives that focus on the "who," "what" and "how" of processes to drive improvement opportunities for implementation and adoption of the program.

Strategic Goal 4:

Provide local enterprise leadership and other research-related stakeholders with decision support tools driven by an authoritative data source

Goal 4 Objectives

- Develop an authoritative data set for dashboards
- Create data dictionary
- Improve current dashboards
- Develop a data interface to retrieve data from other systems into the VAIRRS dashboard
- Create a mobile dashboard

Possible Goal 4 KPIs

- Increase accessibility of dashboards for decision making
- Decrease data inaccuracies and deviations within dashboards
- Increase number of dashboard users
- Increase number of operational queries

VAIRRS recognizes the importance of providing local and enterprise leadership and other research-related stakeholders with a centralized authoritative data source that drives data analytics and decisions. VAIRRS acknowledges the critical need to provide accurate, reliable and trustworthy data for VA leaders and research-related stakeholders to make well-informed decisions.

VAIRRS provides dashboards that offer users customized and tailored data metrics, analytics and decision-making tools. The VAIRRS approach to dashboards ensures they are self-updating and automated (lean) without the need for service providers to update metrics or sources. VAIRRS dashboards will also stand the test of time without the need for redevelopment.

As VAIRRS evolves, dashboards will be updated based on the emerging needs of VA research and its stakeholders. VAIRRS' initial priority focused on training, described in goal one, will help educate a generation of research experts that will have the resources to commit to a reliable authoritative data source. VAIRRS will serve as the established data source for all research-related activities within VA.

Strategic Goal 5:

Promote the local and enterprise value and use of VAIRRS

Goal 5 Objectives

- Promote a strong brand identity
- Increase promotion and engagement with end-users through proactive program-building initiatives
- Analyze website and newsletter metrics to guide future strategy
- Sustain Ambassador Program
- Develop a top performer recognition program
- Create multimedia features to highlight program success in an innovative, eye-catching way

Possible Goal 5 KPIs

- Increase website traffic
- Improve web metrics (bounce rate, time spent on page, downloads)
- Increase newsletter subscribers and open rates

VAIRRS strives to promote the local and enterprise value and use through increasing visibility of VAIRRS programming, opportunities and updates among key stakeholders. The communications strategy establishes VAIRRS as the go-to resource for advancements in VA research, illustrating the value of VAIRRS in the research industry and highlighting VA efforts to improve the lives of Veterans by increasing access to VA research. Communication initiatives, such as the VAIRRS Ambassador Program, which features sites that have successfully transitioned and adapted to VAIRRS, aims to enhance VAIRRS messaging and connect users and facilities nationwide. Opportunities for federal recognition and awards will be identified and sought out to publicize achievements and strengthen the VAIRRS reputation within the industry. Standardized communications collateral (e.g., document templates, presentation templates, style guide) have established a strong brand identity for the program and will continue to be expanded and implemented to maintain consistency and quality in VAIRRS content and communications.

VAIRRS communications is also on track to expand the VAIRRS multimedia and digital portfolio to include content that solidifies VAIRRS as the trusted platform and data source for all research-related stakeholders. Customized video messaging for technical guidance, public service announcements on the research benefits of VAIRRS implementation, and annual video announcements that recap the year's activities will highlight VAIRRS accomplishments. Additionally, a user satisfaction survey will be developed to gauge audience satisfaction and feedback regarding VAIRRS communications and programming. VAIRRS will continue to regularly monitor and evaluate essential communications outputs, measure the impact of activities and identify areas for improvement.

Strategic Roadmap for VAIRRS

To continue to support end-users and promote the program as the single source for research information, VAIRRS developed an objective roadmap to support the implementation of strategic goals. For the remainder of FY22, VAIRRS will facilitate access to existing training tools, increase end-user adoption, ensure access and improve data accuracy. As part of this plan, VAIRRS will develop role-based training and review feedback toward a redesign of the SharePoint portal. Upon establishing the VSAC, council members' expertise and insights will be leveraged for development of future improvements. VAIRRS' communications will continue to strengthen brand identity, develop and implement communications plans for various stakeholders, and create new communications collateral to support end-users. Relating to dashboards, VAIRRS will complete the data dictionary and transition to a single authoritative data source.

As VAIRRS continues to advance role-based training alignment, the program will explore new opportunities to provide additional training and other means for sharing knowledge with users beginning in early FY23. The program will also review the support inbox for improvements, launch the best practices sandbox, test a new prototype for a relaunch of the SharePoint portal and develop criteria for site support. As new processes are developed and implemented, they will be documented in standard operating procedures (SOPs). Once the transition to a single authoritative data source is complete, VAIRRS will begin assessing opportunities to evolve dashboards.

In FY23, VAIRRS will launch a mentor program and begin to develop site profiles. Site profiles will offer VA leaders a more comprehensive look at each individual research site, focusing on the research conducted at that site and the individuals supporting that research. VAIRRS dashboarding efforts will explore the feasibility of absorbing information from other systems, while communications will expand the Ambassador Program to offer recognition to sites and individuals that have performed at an exceptional level. At the end of FY23, VAIRRS will assess the feasibility of a mobile dashboard tool and VAIRRS leadership will review the staffing model across the program to evaluate areas for improvement.

FY24 will begin with a review of this strategic plan and adjustments for the remainder of FY24 and beyond. The following page spotlights objectives under each programmatic area for FY22 through FY24.

Figure 2. Roadmap of proposed objectives per quarter (Q1-4). Asterisks (*) symbolize objectives that are ongoing from FY22 to FY24.

Strategic Objectives

Q3 FY22

- Maintain navigational guides*
- Maintain the VAIRRS Learning Library*
- Manage VAIRRS inbox*
- Establish VAIRRS Strategic Advisory Council (VSAC)

- Provide site support*
- Improve current dashboards*
- Promote a strong brand identity*
- Sustain Ambassador Program*

Q4 FY22

- Develop role-based training curriculum maps
- Maintain Monthly Learning Calendar*
- Facilitate collection and dissemination of best practices
- Optimize and manage the VAIRRS SharePoint*

- Develop an authoritative data set for dashboards
- Create data dictionary

Q1 FY23

- Revamp and grow Mentor Program
- Improve the standardized library of forms and templates

- Develop a mechanism to catalog feedback regarding VAIRRS functionality
- Monitor accurate completion of wizards

Q2 FY23

- Develop a staffing model for VAIRRS
- Develop a repository of site profiles

- Increase promotion and engagement with end-users through proactive program-building initiatives

Q3 FY23

- Maintain strategic plan
- Develop a top performer recognition program

- Analyze website and newsletter metrics to guide future strategy*

Q4 FY23

- Expand VAIRRS data utilization across other VA programs

- Develop a data interface to get data from other systems into the VAIRRS dashboard

Q1 + 2 FY24

- Create a mobile dashboard

- Create multimedia features to highlight successes in an innovative, eye-catching way

Conclusion

VAIRRS aims to elevate VA research to the next level by providing powerful tools that facilitate the work of research oversight committees and increase research collaboration and efficiency across VA. Improving mechanisms for accurate data entry and maintenance will help ensure that dashboards are complete and precise, helping VA leaders make informed research-related decisions. VAIRRS will enable VA to continue its leadership in clinical research throughout the United States by providing organizational structures, trainings and other resources to continually improve research processes across the enterprise.