

**VETERANS AFFAIRS (VA) Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD)
Request for Applications**

Purpose and Scope

The objective of this program is to establish a VA enterprise wide Coordinating Center to direct and manage the VA Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD) program. The Coordinating Center will be funded through the VA Office of Research and Development (ORD) and will be responsible for facilitating ORD's enterprise strategy for research on COVID-19, as well as other infectious and emerging life-threatening diseases. Key elements of VA SHIELD include central and local biospecimen repositories; a central data registry; a network of scientists and subject matter experts, as well as governance and specimen and data access mechanisms. Key responsibilities of VA SHIELD include development and implementation of plans establishing the needed resources, supporting communications, and data/specimen collection and sharing. Its operations will be supported by staff at the central (ORD) and local levels and with an oversight committee structure. The Coordinating Center will report to a VA ORD Program Officer and seek and implement guidance and advice from the two established governance committees, the Executive Steering Committee (ESC) and the Programmatic and Scientific Review Board (PSRB).

The successful team will fulfill the vision of VA SHIELD by initially creating and managing a comprehensive repository of COVID-19 and followed by other infectious and emerging life-threatening diseases specimens and associated data available. Specimens stored in VA SHIELD are to be used to advance scientific understanding in support of developing diagnostic, therapeutic and preventative strategies for immediate deployment in clinical environments. The VA SHIELD Coordinating Center will serve as a key operational partner for ORD in effectively leading VA SHIELD toward overall goals as functioning as a VA research enterprise resource for biospecimen collection and analysis.

Desired outcomes:

- Effectively collect, process, distribute, utilize, analyze, and store collected specimens and other accompanying health data.
- Oversee and direct the effort to ensure that VA SHIELD samples are used for their maximum productivity aimed at clinical utility. Working with the PSRB and ESC to balance the conflicting goals of using the repository samples for projects and the desire to save samples for important future scientific inquiry.
- Work collaboratively with local site investigators and individuals associated with VA SHIELD Central IRB-approved protocols.
- Increase the number of collaborations between VA sites and investigators, key partners, and external collaborators. Engage in harmonizing internal and external efforts between VA entities and studies, biobank biospecimen, and data repositories.
- Increase the scientific impact of VA research efforts including facilitating the careers of junior and trainee researchers.
- Establish VA SHIELD efforts as a foundational entity considered for both individual and cooperative grants and funding.
- Establish VA SHIELD as a premiere VA resource of health data and information that can be utilized by all VA entities and key external partners.
- Establish and adhere to established quality clinical and laboratory standards.

- Contribute to the improvement of patient outcomes through the facilitation of studies resulting in development of diagnostic, therapeutic, and preventative strategies for rapid implementation in clinical environments.

Each application is required to demonstrate the core competencies such as a robust leadership plan, organization and program integration, recruitment, data management and security, review and fulfillment of sample requests, oversight, and process improvement necessary to fulfill the objectives of VA SHIELD. The proposed VA SHIELD Coordinating Center must possess the necessary operations, program management, business, regulatory, and scientific expertise with a documented track record.

Successful applications will include the following elements:

Director, VA SHIELD: The VA SHIELD Director is responsible to the Chief Research and Development Officer (CRADO) through the ORD Program Officer for executing key operational, regulatory, and management tasks of the biorepository. The VA SHIELD Director serves as an advisor to ORD on a wide range of topics including strategic planning, budget management and oversight, performance measures and productivity, staffing, and organizational improvements. The VA SHIELD Director will oversee and work with the three Associate Directors. In addition, the incumbent will work in conjunction with the two governance committees, the ESC and the Programmatic and Scientific Review Board (PSRB) as necessary for operational activities and strategic planning, establish the programmatic priorities and scientific agenda, assess outcomes and measures, and review overall VA SHIELD performance and management. The Director would be responsible for executing strategic plans set forth by the ESC, PSRB and ORD. The VA SHIELD Director will be responsible for maintaining a state of readiness for work contributing toward the solution of disease problems beyond the current COVID-19 pandemic. The incumbent shares a collegial, collaborative, and fully informed relationship with the ESC and ORD leadership; participates in a partnership of duties; and represents VA SHIELD in intra- and inter-agency contacts, as well as with partners and prospective partners who are outside the US Government.

Associate Director for Operations: The VA SHIELD Associate Director for Operations is responsible for the day-to-day management of VA SHIELD across all sites including management of operations, oversight of budget and resources, communications development, oversight of program activities, including ensuring deliverables and milestones set out by the strategic plan. Adherence to the governance guidance and process management activities, including maintaining training portfolios, are the responsibility of the incumbent. The Associate Director for Operations is responsible for in-depth and ongoing operation of VA SHIELD by overseeing formal processing of access requests; overseeing coordination of activities and consultations as needed; identifying challenges and opportunities, outlining potential new approaches for SHIELD utilization and operations, and highlighting potential impacts on departmental or national issues and/or decisions.

Associate Director for Biospecimens: The VA SHIELD Associate Director for Biospecimens is responsible for the day-to-day management of VA SHIELD's processes as it pertains to sample and data management and overseeing the completion of access requests. The Associate Director for Biospecimens is responsible for in-depth and ongoing operation of VA SHIELD by overseeing laboratory and quality processes including formal processing of access requests including quality assessments of samples and data; delivery of samples to and from the biobanks; ensuring adherence to VA rules, regulations, and guidances; monitoring biorepository utilization; identifying challenges and opportunities, outlining potential new approaches for VA SHIELD utilization and operations, and highlighting potential impacts on departmental or national issues and/or decisions.

Associate Director for Data & Informatics: The VA SHIELD Associate Director for Data & Informatics is responsible for data management, informational systems and equipment management and oversight, performance measures and productivity, staffing, and organizational improvements. The VA SHIELD Associate Director for Data & Informatics works in conjunction with the VA SHIELD Honest Broker to approve, distribute or provide access to samples and appropriate patient level data. The VA SHIELD Associate Director for Data & Informatics will coordinate VA SHIELD efforts with the ORD Informatics Enterprise.

The Associate Directors will report to the Director.

Application Information

Eligibility

- Multi-PI, multi-site collaborations are encouraged.
- The Coordinating Center personnel must have expertise in biorepositories, administration, the VA LIMS system, or research related to infectious and other emerging diseases.
- Diversity in collaborations are encouraged.
- The Coordinating Center Director and Associate Directors must be or become VA-salaried investigators at VAMCs or VA-approved sites.
 - Upon initiation of the Coordinating Center the Director and Associate Directors must have a VA paid appointment of at least 25 hours per week (5/8ths) to receive ORD research funding (VHA Program Guide 1200.15). Contract clinicians are not VA employees.
 - The VA employment status, along with anticipated changes if the application being submitted is funded, including 8ths appointment of each Director and Associate Director, must be indicated in the Letters of Support from the Medical Center Directors in the application. If a clinician or nurse Director or Associate does not have a current 5/8ths VA paid appointment, then the Letter of Support from the Medical Center Director must include a commitment to offer the Director or Associate Directors a 5/8ths (or greater) appointment at the VAMC if the application is approved for funding. 8ths contained in the application being submitted may be used to meet this requirement for non-clinicians.
 - Non-clinician Director or Associate Directors are not required to apply for eligibility for this RFA but must have a commitment from the medical center director of the host facility to provide VA employment after funding. For purposes of eligibility, a clinician is defined as a licensed practitioner with a doctoral or professional degree (MD, DO, DDS, PhD, etc.) All others are considered as non-clinicians. Note that the eligibility criteria for this funding mechanism differ from those for most other BLRD funding opportunities.
 - Clinician salary (VA or non-VA) or salary for Nurses or Licensed Medical Professionals (Hybrid Title 38 occupations with clinical appointments) may not be requested in VA-ORD research budgets but must be provided by the local facility as outlined in the required Director's letter of support.
- Applications may be submitted from any VAMC with an active Federal Wide Assurance (FWA) of compliance with the US federal regulations for the protection of human subjects in research.

Application Format

Interested teams should submit applications with the following content:

- Strategic Vision for VA SHIELD (1 page)
- Description of how the VA SHIELD Coordinating Center will be organized, with individuals for each position clearly indicated (4 pages)
- Multi-PI/PD leadership plan (2 pages)
- Research Team and Relevant Experience including [NIH biosketches](#) (2 pages, NIH biosketches do not count toward the page limit)
- Facilities and Resources (2 pages)
- Budget (including a [summary budget worksheet](#)) and budget justification
- Signed Director letter from each participating VAMC, stating an understanding and endorsement of the project, current employment status of key personnel including number of 8ths, and explicit statement of where key personnel are located
 - For Clinicians who are submitting to this application as Director or Associate Director, support of up to 3/8^{ths} may be budgeted understanding that the support is provided through the VERA allocation to the host medical center and salary support would come through the clinical service in which the clinician is employed.
- Letters of Support demonstrating endorsement by national and clinical leaders may be included.
- Metrics to Measure Success. Present a proposed set of measures by which VA SHIELD may be measured annually. The final set of measures will be set in collaboration with the ORD Program officer (1 page)

General Criteria for Review and Scoring of Applications

Applications will be reviewed according to the following criteria:

1. Alignment to VA SHIELD's mission

- *Do the applicants outline a plan that establishes a culture of collaboration with the proposed leadership team, the involved investigators, and other research efforts across the VA Healthcare System?*
- *Does the proposed plan contribute to the effective and efficient operation and organization of a national biorepository system diseases specimens and associated data available to advance scientific understanding?*
- *Does the plan ensure that the Coordinating Center will serve as a key operational partner for ORD in effectively leading VA SHIELD toward overall goals as functioning as a VA research enterprise resource for biospecimen collection and analysis?*

2. Investigator experience, expertise, and capacity to conduct the work

- *Are the qualifications, experience and proposed responsibilities of the Director, Associate Directors and other key personnel well suited to organize, manage and oversee biorepository operations, maintain quality control, provide high quality review of the specimens, ensure appropriate and equitable access to tissue, and track and manage record keeping?*
- *Are the plans for the overall leadership and governance of the tissue bank/biorepository well-thought out? Are the components of the tissue bank/biorepository sufficiently well integrated to ensure efficient operation and successful completion of the project objectives?*

3. Environment and Support

- *Do the environment, facilities, and resources support the requirements enabling the success of the project?*
- *Is there evidence of institutional support reflecting space, equipment, and other unique resources including availability of and access to populations adequate for the project proposed and/or to facilitate collaborative arrangements?*

Additional items may include: *experience working with organizational leadership in developing plans and standards for a national enterprise activity; ability to integrate biospecimen activities with a translational approach to improving care (this item is intended to help shape vision); proposed project plan for meeting initial organizational/start-up and subsequent management goals.*

Other Considerations

In addition to the above criteria, the following additional instructions are provided to reviewers. These items will be considered; however, reviewers are instructed that these items should not influence their overall priority score.

Budget: Are there concerns with the requested budget (amount and duration)? Are there concerns with overlap with other funded activities for any of the key personnel? Is there appropriate justification for all categories of the budget?

Timeline

Applications are due July 31, 2021. Review will be conducted within 30 days of receipt of applications. Funding decision to be made within 15 days of completion of the review. Initiation of Coordinating Center functions within 45 days of receiving funding decision.

Applications must be submitted by the contact PI's local VA Research Office via email to VASHIELD@va.gov. Applications should use the subject line: VA SHIELD Coordinating Center Application.

Applications:

- should be pdfs that are single-spaced, 11-point Arial font, with at least 0.5-inch margins
- should not exceed 12 pages (Biosketches; budget, budget appendix, and budget justification information, supplementary letters, and Director's letters do not count toward the 12-page limit).

Any questions regarding this call for concept papers and funding mechanism should be submitted to: VASHIELD@va.gov

Duration and Budget

Teams will be funded for three years, with a maximum budget of \$600,000 per year. Prior to the conclusion of the three-year funding period, BLR&D may request an application for non-competitive

renewal subject to satisfactory progress. Proposals with smaller budgets that can accomplish the work efficiently are encouraged.

Awardees may request supplemental funding for additional staff once agreed upon initial milestones have been attained. Subsequent milestones, which are developed and approved by VA ORD leadership and the ESC, may include a strategic plan, guidance documents and standard operating procedures, a risk management plan, and a VA SHIELD management plan, which includes clearly defined roles of staff members, ownership and custodian relationships, cost management, intellectual property, publication policy, data sharing, acknowledgments, commercial/industry partnership policies, and training requirements.

Administrative and National Policy Requirements

Research Integrity: VA ORD is committed to the highest standards for the ethical conduct of research. Maintenance of high ethical standards requires that VAMCs and investigators applying for, and receiving, awards have appropriate procedures to preclude the occurrence of unethical research practices. The Director, Associate Directors and others associated with the research must subscribe to accepted standards of rational experimental research design, accurate data recording, unbiased reporting of data, respect for the intellectual property of other investigators, adherence to established ethical codes, legal standards for the protection of human and animal subjects, and proper management of research funds as a condition of acceptance of the award.

Deliberate falsification or misrepresentation of research data will result in withdrawal of an application, possible suspension, or termination of an award, and potentially, suspension of the investigator's eligibility to submit applications to VA ORD.

Acknowledging VA Research Support: By accepting an Award, the Director and Associate Directors agree to properly acknowledge VA affiliation and support in all public reports and presentations ([see VHA Directive 1200.19](#)). Failure to acknowledge VA affiliation and support may result in termination of the Award.

Intellectual Property Rights: By accepting funding for the Coordinating Center, the Director and associate Directors agree to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work ([see VHA Directive 1200.18](#)).

Annual Reports: By accepting an Award, the Director and Associate Directors agree to complete an annual performance progress report.