#### Veterans Affairs (VA) Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA SHIELD) Request for Applications

### Purpose

The purpose of this request for applications (RFA) is to establish new specimen collection sites for VA SHIELD.

VA SHIELD is intended to be a comprehensive repository of biospecimens and associated data in emerging diseases. 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. VA SHIELD is intended to be a flexible ORD resource that can respond to research needs across the VA research enterprise.

As a research enterprise resource VA SHIELD can maximize the collection of highquality specimens and data ethically and efficiently including close monitoring of costs, space, equipment, facility, and personnel needs and reducing research duplication and participation burden on participants, and/or any other identified protected populations.

More information about VA SHIELD may be found at: <u>www.research.va.gov/programs/shield/about.cfm</u>.

Awardees will fulfill the vision of VA SHIELD by participating in strategic planning, SOP development, specimen collections and sharing of comprehensive repository of highquality specimens related to COVID-19 or other infectious and emerging life-threatening diseases specimens and associated data.

Desired applicants must demonstrate their ability to:

- Effectively collect, process, distribute, utilize, analyze, and store collected specimens and other accompanying health data
  - Ideally the site would have an established platform to collect, process, and accession biospecimens into VA LIMS.
  - Ideally the site would have an established platform to collect and integrate multiple types of data, including clinical and illness outcome information.
- Collect quality COVID-19 and other emerging disease biospecimens

Selected applicants are expected to:

- Work collaboratively with other 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

# **Duration and Budget**

• Local collection sites will be funded annually and according to request. Continued participation as a VA SHIELD local collection site will be reviewed annually.

# Eligibility

- Sites must be a part of a tertiary care facility with an annual estimated population of served Veterans greater than 20,000 Veterans.
- VA SHIELD Local Site Investigators must be or become VA-salaried investigators at VAMCs or VA-approved sites.
  - 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.
  - Local site investigators 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.
- 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:

- Type of specimens to be collected, including description of population demographics (250-word limit)
- Statement of interest for joining VA SHIELD (500-word limit)
- Facilities and material resources that the site would be able to contribute or allocate to VA SHIELD (250-word limit)
- Personnel resources that the site would be able to contribute or allocate to VA SHIELD (250-word limit)
  - Key personnel biosketches should be submitted with application, but do not count toward word limit
- What research projects at the site might be interested in cooperation with VA SHIELD (250-word limit)
- Other relevant information on the investigator team and site to support the application. Please present a proposed set of metrics by which the site may be measured annually. Note: the final set of metrics will be set in collaboration with the ORD Program officer (500-word limit)
- Budget (including a summary budget worksheet) and budget justification

Note: Word limit is not restricted in the form; however, word limit will be checked at the time of submission.

Please use the associated application to join VA SHIELD template. In your application submission, please include the completed application template, key personnel biosketches, and a summary budget worksheet with budget justification.

### Summary Budget Worksheet Template:

https://vaww.research.va.gov/funding/docs/SummaryBudgetWorksheetTemplate.xls

Example Budget Justification with Summary Budget Worksheet: https://vaww.research.va.gov/funding/docs/ExampleBudgetJustification.pdf

# **General Criteria for Review and Scoring of Applications**

Applications will be reviewed according to the following criteria:

- 1. Alignment to VA SHIELD's mission
- 2. Access to Veteran population
- 3. Experience, expertise, and capacity to conduct the work
  - Do the proposed local site investigators demonstrate the ability to effectively collect, process, distribute, utilize, analyze, and store collected specimens and other accompanying health data?
  - Does the proposed local site have an established platform to collect, process, and accession biospecimens into VA LIMS?
  - Does the proposed local site have an established platform to collect and integrate multiple types of data, including clinical and illness outcome information?

#### 4. Environment and Support

- Do the environment, facilities, and resources support the requirements enabling the success of the local collection site?
- 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?

#### **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.

<u>Budget</u>: 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

<u>Applications are due July 11, 2022.</u> 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 site functions to begin within 45 days of receiving funding decision.

Applications must be submitted by the contact PI's local VA Research Office via email to <u>VASHIELD@va.gov</u>. Applications should use the subject line: VA SHIELD Collection Site Application.

Any questions regarding this request for application should be submitted to: VASHIELD@va.gov

#### **Administrative and National Policy Requirements**

<u>Research Integrity</u>: 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. Individuals associated with the VA SHIELD 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.

<u>Acknowledging VA Research Support</u>: By accepting funding for efforts associated with VA SHIELD, investigators agree to properly acknowledge VA affiliation and support in all public reports and presentations (<u>see VHA Directive</u> <u>1200.19</u>). Failure to acknowledge VA affiliation and support may result in termination of the site's VA SHIELD status.

<u>Intellectual Property Rights</u>: By accepting funding for efforts associated with VA SHIELD, investigators agree to comply with VA policies regarding intellectual property disclosure obligations and Federal Government ownership rights resulting from the proposed work (<u>see VHA Directive 1200.18</u>).

<u>Annual Reports</u>: By accepting funding for efforts associated with VA SHIELD, investigators agree to complete an annual performance progress report.