## Office of Research and Development Health Services Research and Development Service Program Announcement Request for Concept Papers to Establish Long COVID Practice Based Research Network (PBRN)

1. **Purpose:** VA's Office of Research and Development (ORD) Health Services Research and Development Service (HSRD) seeks concept papers for the establishment of a Long COVID Practice-Based Research Network (PBRN).

Post-COVID conditions, also known as Long COVID, can develop following infection with SARS-COV-2 and result in worse health-related quality of life over time. VHA has established Long COVID clinics or programs to provide multidisciplinary care that is evidence-based and patient-centered. The purpose of the Long COVID PBRN is to reduce barriers and facilitate multi-site Long COVID research that will guide policy and practice at Long COVID clinics and programs.

2. **Background/Rationale:** Many Veterans who have had COVID-19 experience persistent symptoms lasting more than 30 to 90 days after their acute infection. These have been referred to as post-COVID conditions or Post-Acute Sequelae of COVID (PASC) but are most widely known in the patient community as Long COVID. These symptoms can be single or multi-system and include fatigue, shortness of breath, cough, sleep problems, difficulty thinking, diarrhea, and joint or muscle pain, among others. At present, VHA has established approximately 22 Long COVID clinics or programs to provide multidisciplinary care for Veterans suffering from Long COVID, as well as a Long COVID Integrated Program Team to develop plans to ensure that all Veterans have access to appropriate care for persistent symptoms. A Long COVID Community of Practice has also been established to link clinicians leading the efforts to care for Veterans with Long COVID.

Both short-term pilot projects and long-term research are needed to improve Long COVID care. While efforts are underway in the VA and in other Federal agencies, including the NIH RECOVER Initiative, those studies are not likely to generate results for several years. There is an urgent need to capture and analyze near-real-time clinical, operational, and patient-reported data from clinics and programs caring for Long COVID patients. This data can generate insights that can be applied to the care of Veterans as we wait for more definitive research findings.

The Long COVID PBRN will harness the national network of VA Long COVID clinics and programs and their clinical experience along with the methodological and scientific expertise of VA researchers, to pursue the following goals: 1) support and assist Long COVID clinics in data collection and analysis; 2) identify research priorities and questions based on clinical observations of front-line clinicians that can be examined with existing data; 3) document patterns and outcomes of Long COVID care in VA; 4) facilitate and fund short-term pilot studies (≤12 months) to examine patient experiences, clinical presentations, diagnostic investigations and yield of testing,

supportive treatments, and early outcomes, among other issues; and 5) facilitate development and conduct of larger scale research proposals seeking funding from VA and other funding agencies. The PBRN will work closely with the Long COVID Community of Practice and the Integrated Project team to align research efforts with the clinical questions and priorities being generated by front-line clinicians.

- 3. **Eligibility:** This solicitation is open to VA investigators with at least 5/8ths VA appointments at sites with a Long COVID clinic or program. Applications must involve investigators at more than one VA medical center that has a Long COVID clinic or program. Multiple Principal Investigator (MPI) proposals and involving >1 Long COVID clinic are encouraged.
- 4. **Funding**: The PBRN will be funded for 3 years, with potential for non-competitive renewal. Funding is expected to be \$500,000 per year. In addition to administrative costs, the funding is also expected to cover 2 rapid pilots (≤\$50,000 each) per year. Additional pilot funding may be available depending on the availability of ORD funding.
- 5. **Response Format:** A concept paper (4 pages including appendix) is due via email to Christine Nguyen at <a href="mailto:Christine.nguyen@va.gov">Christine.nguyen@va.gov</a>) by **August 29, 2022** articulating in the following order:
  - 1. Title: Response to Solicitation: Establishment of Long COVID PBRN
  - 2. Name of Principal Investigator(s) and Contact Information (e-mail, telephone)
  - 3. List of key personnel, affiliation, role and any special qualifications relevant to the PBRN and COVID research (1 page)
  - 4. Brief description of background and context for studying Long COVID practice and potential to learn from practice-based research. Describe PBRN organization including specific planned activities and anticipated deliverables, the role of each investigator, how data will be collected and analyzed, how communication will be facilitated among sites, and how both pilots and long-term research will be facilitated.
  - 5. Description of any other existing or anticipated partnerships that will facilitate the work of the PBRN.
  - 6. Timeline for first year activities
  - 7. Improvement for Long COVID treatment will require both rapid response studies and longer-term research. Therefore, in a 1-page appendix, provide succinct examples of a short-term pilot project and a long-term project that the PBRN could facilitate.
- 6. **Evaluation:** Concept papers will undergo review by a selected group of VA program officials and scientists. Criteria for evaluation will include:
  - **a. Understanding and approach:** Conveys adequate understanding of the challenges of Long COVID research, critical scientific questions and the potential

contributions of practice-based research. Outlines a feasible approach to producing timely and relevant information to guide VA practice and policy. Supports improvements in collection of standardized clinical data in Long COVID clinics; facilitates learning across collaborative network of clinics; identifies priority clinical questions from engaged partners; addresses new concepts and/or gaps in Long COVID care; and described potential for impact of findings on existing field of research and/or treatment paradigms.

- **b. Personnel and Environment:** Appropriate knowledge/background (e.g., qualifications of team, proposed leadership, steering committee) and resources (e.g., facilities, equipment, institutional support) to ensure completion of work proposed. Appropriate partnerships with clinical teams. Potential to collaborate with and inform other VA researchers and centers, HSRD, ORD, and VHA.
- **c. Management plan:** Appropriate organization of distinct PBRN functions. Appropriate plans to promote coordination and communication of PBRN activities across Long COVID clinics and to partners and other relevant operational and clinical entities. Appropriate plan to collect and use data, as well as to make data available for pilot and larger scale studies.
- d. Proposed projects: Appropriateness and feasibility of proposed projects.

It is anticipated that investigators will be asked to develop a full proposal for merit review and potential funding within six weeks of the date of notification (September 9, 2022) that the concept paper is approved. More details on the format of the full proposal will be released at that time. The proposal is expected to follow standard HSRD merit review instructions, available at: VA-ORD SF424 R&R Application Guide (VA network only) with the exception that the proposal, like the concept paper, will be submitted electronically to <a href="mailto:laura.zimmerman1@va.gov">laura.zimmerman1@va.gov</a> as a PDF file. Proposal reviewers will be asked to identify any major conceptual or other flaws precluding funding and if there are none, to identify any steps needed to strengthen the project.

Questions/Concerns: Questions or concerns can be directed to Christine Nguyen at <a href="mailto:christine.nguyen@va.gov">christine.nguyen@va.gov</a>