Clinical Science Research & Development Site Survey of Potential Participation in PTSD Psychopharmacology Initiative

October 2, 2018

Clinical Science Research and Development Service (CSR&D) is soliciting interest from VA Medical Centers (VAMC) in our PTSD Psychopharmacology Initiative (http://vaww.research.va.gov/services/csrd/ppi.cfm).

If a VAMC is interested in engaging in studies as a site investigator to identify the most effective medications for PTSD in our Veteran population, please complete the sections below and return to Clin-Review@va.gov. Multiple site investigators may be named. The template must be submitted by the local VA Research and Development Service.

A. List Potential Site Investigators' (SI) Contact Information. Include each SI's name, position/title, phone number, and e-mail address.

1. Background and research credentials.

a. Attach a copy of each SI's current biographical sketch

b. Indicate the proportion of time each SI is employed by the Department of Veterans Affairs (in eighths):

2. List of possible site co-investigators. Include each co-investigator's name and position/title.

B. Competing Studies

1. Describe all studies (if any) currently active/planned at your VAMC that may compete with this platform of PTSD medication studies for participants. Provide a plan for conducting these studies simultaneously.

C. Clinical and Academic Assets

1. Is your site a CSP Node Site? Yes ☐ No ☐

2. Is your site an MVP recruitment site? Yes ☐ No ☐

3. Is a study coordinator in place who would be available to work on a new PTSD medication study? Yes ☐ No ☐

    a. If yes, provide name and indicate time (in eighths) that can be committed by the coordinator.

4. Describe additional clinical and academic assets of your VAMC and hospital that enhance the likelihood of successful study activity at your site. Indicate if any special resources are in place for recruitment.

5. List all other clinical trials in which any SI was involved during the past 3 years, and in what capacity he/she participated.

D. Clinical Characteristics

Provide estimates of the following for your VAMC.

1. How many unique patients with PTSD are typically seen in your outpatient clinics in a month? Please cite source of the data.

2. Do you foresee any difficulties in prescribing medications for treatment of PTSD as monotherapy or in combination with another treatment for a clinical trial?

3. Are there any barriers that might prevent your medical center from enrolling patients with PTSD over the recruitment period?

E. To be eligible to participate in a PTSD medication trial, the ACOS for R&D; Chief, Mental Health Service; and Medical Director must assure that your VAMC will be able to satisfy the following conditions:

- The potential VA site investigator who has been identified will have protected time to commit to the study.
- There will be sufficient staff, clinic space and facilities to enroll PTSD patients.
- There will be cooperation from other Services at this VAMC to provide support to conduct this research, such as Research Pharmacy support to manage prescriptions of study medications and IRM support for workstations connected to the VA network for study personnel.

Survey submitted by:

Electronic signatures:

ACOS/R&D

Chief, Mental Health Service

Medical Center Director