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CRA Quarterly Progress Report: 09/01/2022 – 09/30/2022

Pragmatic Trial of Cannabidiol and Tailored Cannabis Coaching to Improve Chronic Pain Symptoms

Kevin F. Boehnke, PhD, Lead Principal Investigator
Rachel Bergmans, PhD, Co-Principal Investigator
Amy Bohnert, PhD, Co-Principal Investigator

Our contract was finalized and signed in early September 2022, so we have begun the process of starting up the many portions of our project.

1. **Percent of completion of the project objectives. This should include a brief outline of the work accomplished during the reporting period and the work to be completed during the subsequent reporting period.**

   We have made considerable progress in the three active weeks of this award. Activities completed include:

   - Start-up: We have set up weekly meetings with the study PIs (Drs. Boehnke, Bohnert, and Bergmans) to begin coordinating all portions of this large study and resolve any issues that arise each week.
   - Hiring project staff: We identified and hired a program manager for this study, who will be starting on October 17th, 2022. This program manager will help oversee the project, write and revise study protocols, coordinate with regulatory bodies (e.g., Institutional Review Boards and the Food and Drug Administration), and help oversee study staff.
   - Beginning development of the behavioral intervention: Drs. Boehnke, Litinas, McAfee, and Ms. Thomas have had weekly meetings to develop and manualize the behavioral intervention meant to help Veterans optimize their self-directed use of medical cannabis products for pain management. We are currently drafting the manual and refining the intervention, with the goal of piloting the intervention sometime in late Q1 or early Q2 of 2023.
   - Meetings with the Michigan Investigator Assistance Program (MIAP) at University of Michigan, which handles Investigational New Drug (IND) and Investigational Device Exemption (IDE) submission to the Food and Drug Administration (FDA): Dr. Boehnke has met several times with the MIAP team to start the process of protocol development for the proposed interventions. The study team and MIAP will work together to develop protocols, with the goal of refining these protocols for IND and/or IDE submission within the next 6 months.
   - Developing registry protocol for aiding with clinical trial study recruitment: We have drafted the protocol for the registry which will support clinical trial recruitment, and anticipate submitting it to the IRB in the next reporting period.

- We have contacted DEA-licensed cannabis grow and processing facilities to find a source of cannabidiol (CBD) study medication that is derived from marijuana (i.e., cannabis with >0.3% THC). We have identified several such facilities that can provide such a product and are currently obtaining quotes to ensure the most competitive price. We anticipate receiving a quote and initiating the IND process in the next reporting period.
- We have met with Veterans, healthcare providers, scientists, and policymakers to start building our community advisory board that will help with study oversight, recruitment and retention, and results dissemination. We anticipate that our first community advisory board meeting will be in Q1 of 2023.

2. **Brief description of problems or delays, real or anticipated, which should be brought to the attention of the Grant Administrator.**

    - In response to feedback from stakeholders and the State, we will not obtain our CBD study medication from cannabis that has <0.3% THC (hemp), and will instead of use CBD study medication that is derived from cannabis with >0.3% THC. As described above, we have already found several potential sources of study medication that meets these requirements.

3. **Statement concerning any significant deviation from previously agreed-upon Statement of Work.**

    - None except the change in study medication noted above.

4. **Financial expenditures of grant money and other contributions to the project, in-kind and/or direct funding.**

    Funds were expended for personnel time.

    $4,352 – Direct Costs for Q3
    425 – Indirect Costs at 9.77%
    $4,777 – Total Q3 Expenditures

We look forward to continued progress on this project over the next quarter.

Sincerely,
Kevin F. Boehnke, PhD
Research Assistant Professor, Director of Controversial Compounds,
Department of Anesthesiology
University of Michigan