Project Title: Advancing clinical and translational science by improving clinical trial research recruitment through innovative community-engaged approaches

Fellow: Jennifer Kraschnewski, MD MPH; Penn State College of Medicine

Penn State Collaborators and Mentors:

Kevin Black, MD; Interim Dean, College of Medicine Lora Weiss, PhD; Senior Vice President for Research, Penn State University Michael McShane, MD EdM; Assistant Professor of Medicine, College of Medicine Mark Stephens, MD MS; Associate Dean for Medical Education, College of Medicine Jennifer Poger, Med; Senior Project Manager Andrea Murray, MPH; Community Engagement Coordinator CHEER Community Partners

Significance:

Patient recruitment is a key determinant of clinical trial success. Unfortunately, up to 86% of clinical trials do not reach their recruitment targets on time. Further, clinical trials continue to primarily enroll white men, with consistent underrepresentation of women, the elderly and people of color. One of the limitations of research participant diversity is that the vast majority have been conducted within academic medical centers, demonstrating we need to move outside of our traditional approaches. Achieving representativeness within our clinical trials is critical to ensuring no patients are left behind with clinical treatment advances.

Increasing community engagement in recruitment efforts offers potential for innovative approaches. Enhancing the patient-centeredness of clinical trial recruitment requires overcoming known barriers to participation, including travel to trial sites. One approach is to leverage mobile health clinics (MHCs), which serve as a bridge between the clinic and community. MHC patients are mostly women (55%) and racial/ethnic minorities (59%), presenting a unique opportunity for creating connections and building trust between research and underrepresented populations. Creating satellite clinical research centers and engaging established community health workers to assist with recruitment are additional potential approaches.

Purpose/Goal/Objectives:

The purpose of this project is to assist the College of Medicine with clinical trial recruitment, leveraging community-engaged approaches to ensure greater representativeness of research participants. The short-term project objectives include pilot testing the MHC as a potential clinical trial recruitment mechanism to determine feasibility and acceptability.

Methods/Approach/Evaluation Strategy:

This project was conducted in collaboration with the CHEER (Community Health Equity & Engagement in Research) Initiative and the MHC team. Engaging these teams facilitated the development of reciprocal relationships necessary for successful community engagement to build trust and support recruitment. Activities accomplished included:

1. Successful partnership with the Human Research Protection Program to facilitate study recruitment through the MHC.

- 2. Identification and pilot testing of three appropriate clinical trials with MHC recruitment.
- 3. Exploration of a satellite clinical research center in downtown Reading, Pennsylvania.
- 4. Development of an approach to engage externally-employed community health workers in clinical trial recruitment.

Outcomes/Results:

The pilot testing resulted in the identification of three clinical trials which were interested and appropriate for MHC recruitment. All three trials received IRB approval for MHC recruitment, leveraging our team's standardized protocol language. The trials were promoted at five MHC community events in December and January. In total, 48 recruitment flyers were distributed and the CHEER staff engaged with 13 potential research participants representing our priority population.

Discussion:

Early results demonstrate the feasibility and acceptability of clinical trial recruitment through the MHC. Ongoing MHC events are planned to continue to present recruitment opportunities to patients. Next steps towards the establishment of a comprehensive "front door" for research recruitment will include expanding MHC efforts. Additional approaches to community-engaged recruitment, including creating satellite clinical research centers and leveraging community health workers, require exploration.

Summary/Conclusion:

Successfully connecting to communities through reciprocal relationships is an important goal for increasing representativeness in clinical trials and can be accomplished through MHCs and potentially other innovative approaches.