

## **Clinical Trial Nurse Navigation and Outreach to Increase Participation of Underrepresented Populations in Research**

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### **1. Background**

Despite progress on equitable patient participation and recent FDA guidance that mandates increased clinical trial diversity, underrepresented population participation is still lacking. Multiple systemic barriers contribute to this, including limited access to care, social determinants of health (SDOH), complex health care systems, mistrust, decreased health literacy, and restrictive eligibility criteria. The HICCC serves a highly diverse catchment area with deep roots in local communities and robust Community Outreach and Engagement (COE). Our enrollment reflects this with 40 percent from underserved populations. Clinical Trial Nurse Navigation can assist in overcoming enrollment barriers and further increase representation.

### **2. Goals**

- Facilitate greater access to clinical trials
- Identify trial opportunities for patients
- Develop comprehensive recruitment plans for individual studies with a focus on investigator-initiated studies
- Provide community-focused education paired with outreach regarding clinical trials, liaise with community providers to increase clinical trial awareness, and increase trial diversity

### **3. Solutions and Methods**

Clinical trial nurse navigators at HICCC collaborate with multiple stakeholders to facilitate clinical trial enrollment and address barriers to diverse representation.

- **Access:** Dedicated clinical trial nurse navigator phone and email centralize first point of contact for clinical trial inquiries from prospective patients, family, providers, organizations, or other referrals.
- **Systems:** The navigation team collaborates with the HICCC Bioinformatics team on multiple levels using genomic information to match studies with prospective patients. One notable collaboration also includes our COE office. DISRUPT Diversity & Inclusion in Research Underpinning Prevention and Therapy Trials. This project aims to disrupt the systemic barriers to enrolling diverse populations.
- **Community Outreach:** We partner with the COE office to provide clinical trial education activities in varied community settings. In 2023, the navigation/outreach core organized the first annual Diversity in Clinical Trials Day, to cultivate a space for the community, patients, staff, providers, and industry to engage in bi-directional conversation about the importance of clinical trial diversity and overcoming barriers to diverse enrollment.
- **Targeted Outreach:** We are also partnering with our institution's physician outreach liaisons to build relationships with local providers and pair them with a streamlined referral process and clinical trial education.

- Collateral Materials: The navigation and outreach team have created various resources (e.g., pamphlets, flyers, social media posts, and presentations) for varied audiences and settings. The goal of the materials is to provide education and increase clinical trial diversity.
- Trial selection: Our team is reporting on metrics collected to inform clinical trial selection, creation and providing input into Investigator-Initiated Trials (IIT) trial eligibility and feasibility.

#### **4. Outcomes**

In 2023, we onboarded 3 full-time nurse navigators to cover 12 disease-based teams. This team addressed 627 trial inquiries and assisted in enrolling 115 patients (18 percent of total interventional trial accruals). With a shift to an active patient recruitment model, we expect to increase navigator activity by 50 percent in 2024 and contribute to an increase in overall trial enrollment focused on our diverse catchment area.

#### **5. Lessons Learned and Future Directions**

Enrolling underrepresented populations takes considerable time, effort, and resources. Navigation is one tool in the arsenal to help address disparities and facilitate enrollment. Technological advancements will certainly help achieve these ends but not without the human connection that nurse navigators can provide.