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Eugene Washington PCORI Engagement Award, Contract # 1107
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This manual is dedicated to the memory Dr. Trevor K. Thompson, sickle cell warrior and champion for the sickle cell community. Without his devotion and efforts to support sickle cell consumers this work would not have been possible.
Acknowledgement

This manual was created through a collaborative process that included members from Vanderbilt University, Vanderbilt University Medical Center, the Sickle Cell Foundation of Tennessee, as well as members of our foundation advisory boards in Chattanooga, Nashville, and Memphis. Many thanks to all of you for your insights, suggestions and review. We could not do this work without you.
To Researchers and Patient Stakeholders

The intent of this manual is to provide researchers and patient stakeholders with a model for engaging underrepresented populations in clinical research. The need to engage patients in clinical research is a challenge that is widely acknowledged among health researchers, yet little attention is focused the engagement of patients with a rare disease. Strategies used to recruit and engage minority populations may work but rare populations are often times invisible and thus new strategies are needed to recruit, engage, and sustain the engagement.

There is no established strategy on how to engage the SCD community in setting the research agenda. Recently, a systematic review was undertaken to understand best approaches for engaging rare disease communities in patient-centered outcomes research. Out of 35 studies identified, there was limited evidence to inform and guide best practices for community/patient engagement. Sickle cell disease (SCD), the most common inherited blood disorder in the United States, was not represented in these studies, and only one study included urban and rural communities but was based in China. Additionally, none of the studies included AAs. There are many reasons for underrepresentation of African Americans in community based research; chief amongst those is mistrust and community stigmatization of certain health problems, including SCD. Despite the prevalence of SCD and its impact on the health care system, little has been done to explore how to engage patient experts to contribute to Patient Centered Outcomes Research, an essential resource for formulating research and service priorities.

The Patient Centered Outcomes Research Institute’s (PCORI) Engagement Awards Program provides a platform to expand the role of all stakeholders in research and encourages active integration of patients, caregivers, clinicians, and other healthcare stakeholders as integral members of the research process. In 2015, the Vanderbilt-Meharry Center of Excellence in Sickle Cell Disease was awarded the PCORI Engagement Award for the “Tennessee SCD Network”.

Patient partners in this study were identified as having an interest in community engagement efforts regarding sickle cell disease (SCD). Through this PCORI project we developed a new strategy for educating rural and urban families about the management of sickle cell disease. We hoped to achieve the following goals:

1) Identify patient partners with SCD in rural and urban communities in TN to establish a virtual, vibrant and sustainable community.
2) Provide human subjects and research basics training to non-research stakeholders across the state.
3) Obtain feedback about practical ways for providing input on research efforts from individuals with SCD and their family members across TN.
4) Develop a scalable web-based patient centered outcomes research (PCOR) process model in order to replicate and implement this in other states.
5) Refer patients with the disease to primary care providers equipped with the knowledge to adequately care for individuals with the disease.

Obtaining feedback strategies to deliver medical service initiatives is a critical gap that is missing in the formulation of stakeholder sensitive PCOR agenda. Conceivably, our initiative would provide a voice to regional and national SCD stakeholders. To initiate the process, we recruited Community Health Ambassadors, residents and representatives of urban and rural communities throughout the state. The recruitment was done primarily through the Patient and Stakeholder
Executive Committee and Sickle Cell Foundation of Tennessee. Community Health Ambassadors served as contacts/liaisons between the Sickle Cell Foundation of Tennessee and SCD patient partners. Community Health Ambassadors have been used in our previous work in African American communities and have been invaluable to us in establishing credibility with the residents. In their role, Community Health Ambassadors expanded the outreach and capacity of the Sickle Cell Foundation of Tennessee by working directly with community residents to identify and recruit patient partners. Additionally, Community Health Ambassadors encouraged community members to be actively engaged in the process of providing feedback that can be shared with the Sickle Cell Foundation of Tennessee and SCD research stakeholders to guide future research, educational training, and other relevant needs and interests.

Implementation of a Community Health Ambassador training model was effective in increasing the communities’ knowledge base of SCD and creating active discussions about SCD research agendas with adults and parents of children with sickle cell disease in the state of Tennessee. Ultimately, we hope that our strategy was successfully adapted to other healthcare efforts that may have a positive outcome on sickle cell disease awareness and patient care.

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Trevor K. Thompson, Ed.D.
Executive Summary

Research Objective: Despite the high prevalence of individuals affected by SCD, comprehensive care, education, and training for people diagnosed with SCD is not as widely available as health care services for individuals managing other chronic illnesses. Our study engaged the SCD community stakeholders in PCOR as an essential mechanism for advancing care and meaningful research for this rare disease population. A statewide SCD network was developed to offer social support and increase access to education, medical care, engagement in research activities that affect the lives of SCD patients and their caregivers.

Study Design: We systematically identified patient partners with SCD in rural and urban communities in TN to establish a vibrant and sustainable infrastructure through a partnership with the Sickle Cell Foundation of Tennessee to engage urban and rural areas, with specific focus on connecting the SCD community through a potential service providing community based organization (CBO) to provide: 1) information on how to connect with other families; and be informed about SCD community activities, or educational offerings; 2) training in basic research principals and 3) opportunities to contribute to PCOR, including feedback on effective and practical ways for providing input on research efforts through patient centered input, comparing urban and rural area preferences.

Population Studied: SCD patient partners aged 18-50, of which 30% came from rural areas throughout the state of Tennessee. Additionally, an executive committee, comprised of 87 stakeholders across the 3 regions of Tennessee were recruited to assist in the development of the statewide network, and eventually serve as the governing body of the TN-SCD Network. These representatives include local physicians, community leaders, adults with SCD and parents of children with SCD.

Principal Findings: We engaged 432 patient partners were recruited across all three regions, and 35 executive committee members. Community health ambassadors have utilized health fairs, clinic days at various hospitals and community centers, and social media to spread awareness of the project, in addition to boosting the recruitment process.

Conclusion: Most rural and urban families affected SCD have no systematic way to engage in, or lend their expertise to, patient-centered outcomes research (PCOR). A statewide network of patient partners, community stakeholders, researchers, and medical professionals will ultimately increase the standard of care for patients, and provide valuable insight for sickle cell disease research.

Implications for Policy or Practice: The opportunity to create the underpinnings for coordinated patient-centered education and linking of individuals living with SCD and their caregivers, as well as SCD stakeholders throughout the state of TN holds promise for developing a scalable PCOR process model for replication and implementation in other states the success enabling other states with rare disease populations to emulate this model.
Background

Sickle Cell Disease (SCD) is a group of inherited red blood cell disorders. In SCD, the red blood cells become hard and sticky and look like a C-shaped farm tool called a “sickle”. These cells can get stuck in small blood vessels and block the flow of blood and oxygen to organs in the body. The blockages cause repeated episodes of severe pain, organ damage, serious infections, or even stroke. Sickle cell disease is the most common inherited genetic disorder in the United States, affecting 1 in 365 African Americans (AA) and 1 in 13 AAs affected by sickle cell trait. In Tennessee (TN), approximately 2,157 AAs have SCD, of which 507 reside in rural parts of the state. Despite the high prevalence of individuals affected by SCD, comprehensive care, education, and training for people diagnosed with SCD is not as widely available as health care services for individuals managing other chronic illnesses.

Rarely are patients seen as partners in health research, and even scarcer, is the opportunity for patients with a rare disease to provide their voice in research that informs their health outcomes. Patient Centered Outcomes Research (PCOR) provides a means for patients with rare diseases such as sickle cell to participate in research that directly impacts their health care decisions and outcomes. Patient-centered outcomes research is the evaluation of questions and outcomes meaningful and important to patients and caregivers, including the perspectives of end users of the research, which include patients, physicians, and other health care stakeholders, will enhance the relevance of research to actual health decisions these end users face. “PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.”
The Tennessee Sickle Cell Disease Network project engaged SCD community stakeholders in PCOR as an essential mechanism for advancing care and meaningful research for this rare disease population. In addition, a statewide SCD network is being developed to offer social support and increase access to education, medical care, and engagement in research activities that affect the lives of SCD patients and their caregivers. We systematically identified patient partners with SCD in rural and urban communities in TN to establish a sustainable infrastructure through a partnership with the Sickle Cell Foundation of Tennessee, to connect the SCD community through a service-providing community based organization to:

1) Systematically Identify patient partners with SCD in rural and urban communities in TN to establish a virtual, vibrant and sustainable community;

2) Provide human subjects and research basics training to non-research stakeholders across the state;

3) Obtain feedback about ways for providing input on research efforts from individuals with SCD and their family members;

4) Develop a scalable web-based PCOR process model for replication and implementation in other states.

Figure 1, Organization of Patient Engagement illustrates our model for engaging individuals and families with sickle cell disease. Based on this model, the Sickle Cell Foundation of Tennessee (SCFT) functions as a clearinghouse for interacting with the identified SCD community. Therefore, research stakeholders interacted with the SCFT and SCFT provided coordinated communication between the research stakeholders and the community. Having SCFT serve as the clearinghouse for PCOR initiatives provides a more accurate picture of SCD stakeholder research and service priorities across the state.
Figure 1: Organization of Patient Engagement

SCD Research stakeholders

Sickle Cell Foundation of Tennessee (SCFT)

Community Ambassadors
Statewide outreach

Community engagement:
Rural & Urban needs assessment
Establishing the infrastructure for implementing patient-centered outcomes research

This project sought to engage patient stakeholders during each phase of the research process utilizing the principals of trust, respect, honesty, co-learning, and reciprocity. Thus, we established a partnership with the Sickle Cell Foundation of Tennessee that targets and has access to SCD population (patients, caregivers, advocates, stakeholders).

**Sickle Cell Foundation of Tennessee**

The Sickle Cell Foundation of Tennessee (SCFT) is a charitable, non-profit, 501(c) 3 organization that operates for the benefit of individuals living with Sickle Cell Disease (SCD) in the State of Tennessee and the Mid-South community (East, Arkansas and North Mississippi). The mission of the SCFT is to provide comprehensive social services to improve the quality of life of individuals living with Sickle Cell and educational services to the Mid-South community. The vision of the SCFT is to increase education, health awareness and life skills, promote self-sufficiency, and improve the quality of life of individuals living with Sickle Cell. The organization is one of the premier Sickle Cell Community Based Organizations in the world.

The mission of the Sickle Cell Foundation of Tennessee is to provide comprehensive social services to improve the quality of life of individuals living with Sickle Cell. The vision of the Sickle Cell Foundation of Tennessee is to increase education, health awareness, life skills, promote self-sufficiency, and improve the quality of life of individuals living with Sickle Cell.

**SCFT Advisory Council**

The SCFT Advisory Council is a body that advises the management of the Sickle Cell Foundation of Tennessee. The council consists of individuals and families that are effect by Sickle Cell Disease. Additionally, some medical and community partners serve on the council. Unlike the Board of Directors, the advisory council does not have authority to vote on corporate matters, nor a legal fiduciary responsibility. However, all programs, initiatives and fundraisers
are vetted through the SCFT Advisory Council. Additionally, training is conducted at every advisory council meeting on various topics. SCFT assisted in improving the overall quality of life of individuals living with Sickle Cell by achieving the following: 1) increasing the education of the community about the disease (consumers, healthcare providers, and general public), 2) increasing consumers’ education as it relates to disease and pain management, thereby decreasing emergency room visits and hospitalizations, and 3) implementing needed social support services (soft skills training, professional development, transportation to medical appointments, etc.) that will in turn increase the overall health outcomes of consumers. It is the goal of the SCFT to provide a broader and more comprehensive level of care to its clients. Through these services, consumers will ultimately improve their overall quality of life and life expectancy, enabling them to become productive citizens in their communities.

**SCD Research Stakeholders**

The SCD research stakeholders is a collaborative comprised of: 1) The Patient Stakeholder Executive Committee, 2) Consultants, 3) the SCFT Advisory Council, and 4) Community Health Ambassadors. The project goal of the SCD research stakeholders’ group was to form the TN-SCD Network and assess the needs of the SCD community, using multiple methods to gain an understanding of the needs of the metropolitan and rural individuals affected by the rare disease. The Patient Stakeholder Executive Committee is comprised of representatives from the SCFT, local physicians, adults with SCD, and parents of children with SCD. This committee is the governing of the TN-SCD Network. The Consultants are individuals with SCD or caregivers identified for providing feedback during structured questions. The SCFT Advisory Council is a multi-disciplinary group, whose purpose is to serve as experts to the Research Stakeholders about potential research priorities for the TN-SCD Network. Finally, the SCD Research Stakeholders connections to our targeted community occur through Community Health Ambassadors, who serve as liaisons between each component and a conduit for
between SCD patients and avenue for SCD patients and family members to provide feedback and other pertinent information to SCD Research Stakeholders.

**Community Health Ambassadors**

SCFT facilitated the recruitment of Community Health Ambassadors (CHA). The Director of the SCFT identified and recruited trusted community leaders who were: 1) willing and able to volunteer to be trained as lead, regional, and local CHAs; and 2) would promote health with respect to SCD. CHAs were primarily responsible for identifying, recruiting, and engaging SCD patients as partners. Ambassadors comprised of patients with SCD, caregivers of a patient with SCD, community advocates for SCD, individuals with an existing relationship with the foundation and experience advocating for individuals with the SCD, and individuals with strong links in the rural Tennessee community. The CHA served as liaisons between the SCFT and SCD patient partners. CHAs have been used in our previous work in African American communities and an invaluable resource to gain access to and credibility with these communities. In their role, CHAs expanded the outreach and capacity of the SCFT by working directly with community residents to identify and recruit patient partners. Additionally, CHAs encouraged community members to be actively engaged in the process of providing feedback that could be shared with the SCFT and SCD research stakeholders to guide future research, educational training, and other relevant needs and interests.

The CHAs were comprised of patients with SCD, patients with sickle cell trait, parents of children with SCD, community advocates for SCD, and individuals who had an already existing relationship with the foundation and experience advocating for individuals with the SCD, and strong links in rural community. Having patients and members of the sickle cell community participate as CHAs was a critical element to this project, as having a personal connection SCD was essential to establishing trust. The researchers recognized that the difficulties with engaging patients with SCD and their families. Thus, it was determined that those facilitating
contact with patients and their families would also need to patients, caregivers, or known advocates within the community. Incorporating patients and advocates of SCD as CHAs also ensured that information reached the community that needed most. The demographic composition and community type serves is listed in Table 1 below.

### Table 1: Characteristics of Community Health Ambassadors, N = 8

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Range</td>
<td>21-60 years</td>
</tr>
<tr>
<td>Race</td>
<td>African American 8 (100.0)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (25.0)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (75.0)</td>
</tr>
<tr>
<td>Geographic Location</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>6 (75.0)</td>
</tr>
<tr>
<td>Rural</td>
<td>2 (25.0)</td>
</tr>
</tbody>
</table>

Primary responsibilities of the CHAs were: 1) Education and Awareness; 2) Recruitment; 3) Engaging patients stakeholders; and 4) Collaborating with advisory board. Using a multi-modal approach for reaching out to a rare disease community was essential to build the TN-SCD Network as best practices have yet to be established or compared for this population living in either rural or metropolitan communities. At project initiation, we leveraged community engagement methods that have been successful in different contexts, including CHAs training protocols and procedures.

**Training the Community Health Ambassadors**

Members of the research team and the Director of SCFT conducted an eight hour training session for the Community Health Ambassadors each year, at which procedures for recruiting, tracking, and engaging families are reviewed. During the training, CHAs developed strategies and approaches for engaging research stakeholders, and offered suggestions for ways to improve recruitment and retention protocols; they were also given updates about SCD research and treatment protocols for SCD. Specific training goals for Year 1 included: 1) identify effective strategies for engaging 50 families/region; 2) develop strategies for engaging various
constituents to formulate SCD Research Stakeholders in each regions; 3) identify effective ways to use technology as a mechanism for engaging, educating, and involving patients and family members in SCD research; 4) gaining skills on the use of Research Electronic Data Capture (REDCap) to track recruitment and community contacts; 5) how to provide educational sessions for community stakeholders and patients about SCD and testing for sickle cell trait; 6) developing management procedures to reach deliverables based on timeline, including developing action plans to meet project objectives; and 7) brainstorming sessions on the development and design of a Tennessee-SCFT Community Health Worker training program in education and advocacy.

Training in Year 2 presented an opportunity to reassess strategies for engaging patients and caregivers and to assess additional training and resources needed for the CHAs. Training topics included: 1) Develop Strategies for Educating Stakeholders, Patients, and Family Members to be active collaborators in SCD Research; 2) How to effectively implement a Community Research 101 Day in each region; 3) Revisit and Review Approaches and Strategies Implemented in Year 1, focused more on how to enhance strategies that were most effective for engaging patients/families; 4) Discuss lessons learned, including difficulties/challenges engaging families; and 5) Develop action plan for completing final phase of project. In the following section, we provide a detailed description of our CHA training by project phases.

Phase I: Orientation

Once CHAs were identified by Director of SCFT, the research team facilitated the hiring process, through the university employee system. Following hiring approval for each CHA, an orientation was held in Nashville, Tennessee, at which time the CHAs completed employee paperwork, obtained employee badges, and an overview of the PCORI project, methods, and study procedures were provided. Each CHA received training manual tailored for the Tennessee
SCD Network (See Supplement). Elements of the training manual were: Community Health Ambassador’s Charge, Prerequisites, Responsibilities and Duties, Preparing to Launch Your Role as a Community Health Ambassador, Recruiting, Reporting Activities, Training Supplements, and Compensation.

Phase II: Human Subjects Training

As members of a research team, CHAs were required to complete Human Subjects training. Vanderbilt University Community Engagement Research Core (CERC). CERC, in partnership with Meharry Medical College and the Vanderbilt University Medical Center, is designed to bring academic and community partners together to improve community health and healthcare through research. CERC has developed a Protection of Human Subjects curriculum specifically tailored for non-academic, community members who are partnering with academicians in research efforts. This training program has been approved by Vanderbilt University’s Institutional Review for offering educational training that ensures community members, who are engaging in research, have adequate knowledge for the protection of human subjects during each of phase of research. Similar to the process for that academic researchers have to complete through the CITI training, community members completed a quiz assessing their knowledge of protection of the human subjects following the training. In order to be certified, trainees much score 80% correct. Quizzes are completed by a certified member of the CERC IRB staff, and those receiving at least 80% correct are given an IRB certification number, and are entered as key personnel on respective Vanderbilt University Human Subjects’ approved project file. The CERC IRB Staff person conducted the training in a virtual classroom setting. Although a physical classroom setting is preferred, as it allows for immediate, face-to-face interactions between instructor and community members, this option was elected to overcome location barriers (e.g., different geographical locations of CHA’s in Tennessee and difficulties in finding a central location that was conducive to all CHAs).
Phase III: Field Work and Supervision

Ambassadors received training on field responsibilities and organizational structure (Figure 2). This training consisted of receiving role assignments as local ambassadors, regional ambassadors, and lead ambassadors. Assignments were determined based on experience advocating for patients with SCD, working with a community-based organization, and amount of time that could be devoted working with a leadership role. The organization structure also indicates the flow in communication and levels of supervision. The lead ambassador served as a liaison between the SCFT and regional CHAs, while regional CHAs served as liaisons between the lead CHA and the local CHAs.

Figure 2: Approach Overview

Figure 2: Conceptual model for engaging SCD patients residing in urban and rural communities. Adapted from Murry, V.M. (2011, December). Stigma and Distrust: Engaging Marginalized
Populations in Research and Prevention presented at the NICHD Health Outcomes among Children and Families Living in Rural Communities, National Conference, Bethesda, MD
Recruitment

Members of the research team, including Director of SCFT and CHAs, systematically identified patient partners with SCD in rural and urban communities in TN to establish a vibrant and sustainable infrastructure through a partnership with the Sickle Cell Foundation of Tennessee to engage urban and rural areas. Specific consideration was given to connecting the SCD community through a potential service providing community based organization (CBO), namely SCFT, to provide: 1) information on how to connect with other families; and be informed about SCD community activities, or educational offerings; 2) training in basic research principals and 3) opportunities to contribute to PCOR, including feedback on effective and practical ways for providing input on research efforts through patient centered input, comparing urban and rural area preferences.

SCD patient partners were aged 18-50, of which 30% came from rural areas throughout the state of Tennessee. Additionally, an executive committee, comprised of 87 stakeholders across the 3 regions of Tennessee were recruited to assist in the development of the statewide network, and eventually serve as the governing body of the TN-SCD Network. These representatives include local physicians, community leaders, adults with SCD and parents of children with SCD.

Community Health Ambassador Strategies

A total of 150 patient partners were recruited across all three regions, and 35 executive committee members. Leveraging different strategies to establish a SCD-Network not only ensures the success of connecting individuals and caregivers throughout the state affected by SCD, but also allows for identifying the most appropriate and effective strategies and approaches to recruit and engage patients/family members residing in rural and urban areas. For example, social media, churches, and hair salons are effective in reaching participants in both geographic settings, however, community health ambassadors utilized health fairs, clinic
days at various hospitals and community centers, and social media to spread awareness of the project, in addition to boosting the recruitment process (Table 2).

Table 2: Strategies to identify and enroll patients and family members

<table>
<thead>
<tr>
<th>STRATEGY TYPE</th>
<th>URBAN CHAS</th>
<th>RURAL CHAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Media</td>
<td>Facebook</td>
<td>Facebook</td>
</tr>
<tr>
<td></td>
<td>Twitter</td>
<td>Twitter</td>
</tr>
<tr>
<td></td>
<td>Instagram</td>
<td>Instagram</td>
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<tr>
<td></td>
<td>Foundation Website</td>
<td>Foundation Website</td>
</tr>
<tr>
<td>Community Events</td>
<td>Community Health Fairs</td>
<td>Church Health Fairs</td>
</tr>
<tr>
<td></td>
<td>Community Fairs</td>
<td></td>
</tr>
<tr>
<td>Medical Facilities</td>
<td>Federally Qualified Health Centers</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Hospital Clinics</td>
<td>N/A</td>
</tr>
<tr>
<td>Faith-based Organizations</td>
<td>Churches</td>
<td>Churches</td>
</tr>
<tr>
<td>Community Organizations</td>
<td>Beauty Shops</td>
<td>Beauty Shops</td>
</tr>
<tr>
<td></td>
<td>Barber Shops</td>
<td>Barber Shops</td>
</tr>
<tr>
<td>Qualitative Input</td>
<td>Community Engagement Studio</td>
<td>Focus Groups</td>
</tr>
<tr>
<td>Other</td>
<td>Email Blasts</td>
<td>Email Blasts</td>
</tr>
<tr>
<td></td>
<td>Flyers</td>
<td>Flyers</td>
</tr>
<tr>
<td></td>
<td>Newspaper Flyer</td>
<td>Radio Segment</td>
</tr>
</tbody>
</table>

Activities for Launching Community Outreach Efforts

Contact hematologists and community clinic: Reaching out to hematologists and community clinics in both rural and urban populations including providing pamphlets and education about the Sickle Cell Foundation of Tennessee mission and support services; as well as opportunities to participate in shaping research initiatives with input via the Community Health Ambassadors or patient-focused conference; both funded through this initiative. The lead Community Health Ambassador was hired as part of this grant to: 1) engage all stakeholders to review the pamphlets and educational material created; 2) drive to the identified areas and provide the
materials; and, 3) collect information on areas that may be in need of support services and want to participate in research. The Community Health Ambassador identified hematologists and community health centers that are in area codes with high percentages (>10%) of African Americans that are willing to assist with the efforts of this proposal.

**Contact local newspapers and radio stations and solicit their assistance in providing public service announcements:** Public service announcements (PSAs) were used to encourage individuals to seek additional information through the Sickle Cell Foundation of Tennessee website and a toll-free phone number. Information in the PSA will also describe services provided by The Sickle Cell Foundation of Tennessee website and give the user an opportunity to register with the community based organization. Additionally, individuals can call a toll-free number to provide the same information to the Sickle Cell Foundation of Tennessee. Each person who joins the Sickle Cell Foundation of Tennessee will have the option of having their contact information provided to the Center for Excellence in SCD to receive communication about community based events and initiatives; this also helped grow the SCD community based network.

**Social Media:** The research team developed and launched social networking tools, such as Facebook and Twitter to increase awareness about the Sickle Cell Foundation of Tennessee. Included in the messages were instructions on how to become a member of the Sickle Cell Foundation of Tennessee, and how to participate with the Vanderbilt-Meharry Center of Excellence in SCD research efforts. Social Media also was used to provide coordinated communication about upcoming conferences, virtual town halls, human subject research training and the overall initiative of the TN-SCD network.

**Partnering with Faith Based Organizations:** Each region worked with local churches to establish and coordinate Sickle Cell Sabbath Sundays. Refer to materials in your training packet for instructions on procedures for organizing this event.
Organized central meetings: Each region hosted meeting connect the SCD community and provide educational opportunities.
Engaging Patients, Family Members, and Community Stakeholders

Research partners had an opportunity to participate in community engagement studios to inform the design of the study and provide early feedback on concerns of patients with sickle cell disease. A Community Engagement Studio (CES) is a structured way to obtain input focused on patient related concerns as well as understanding patient perspectives. Questions asked at community engagement studios:

- What are ways that we could build community among patients (or caregivers) with sickle-cell?
- What are barriers to participating in preventive care?
- What do patients and caregivers identify as important issues of concern regarding their health care management?

Feedback from initial phases of patient engagement indicate four areas of patient concern:

1) The need to engage health care professionals in discussions related to treatment protocols.
2) Addressing the needs of pregnant sickle cell patients
3) The need to engage patients as educators
4) The need to engage school systems and personnel

<table>
<thead>
<tr>
<th>Major Themes</th>
<th>Examples of Illustrative Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>The need to engage health care professionals in discussions related to treatment protocols</td>
<td>“... explicitly stating the set amount of dosage and type of medication for participants.”</td>
</tr>
<tr>
<td>Addressing the needs of pregnant sickle cell patients</td>
<td>“Maybe create a checklist of items that must be met before doctors are allowed to discharge patients so each patient is treated in a more uniform way”</td>
</tr>
<tr>
<td>The need to engage patients as educators</td>
<td>“Continuous education of SCD to families with and without the trait in order to increase overall awareness in communities”</td>
</tr>
<tr>
<td></td>
<td>“Train kids on how to advocate for themselves. Empower them to speak up for themselves.”</td>
</tr>
<tr>
<td>The need to engage school systems and personnel</td>
<td>“SCD needs to be taken more seriously, especially in schools where it is overlooked and written off as being a concern of an overprotective parent.”</td>
</tr>
</tbody>
</table>
Through our PCORI Eugene Engagement study, we conducted focus groups with patient with SCD and their caregivers in urban (n=2) and rural (n=2) communities throughout three regions in TN. The purpose of the focus groups was to elicit concerns regarding increasing sickle cell disease awareness, education and research participation, comparing rural and urban communities. See data section for focus group results.

Focus group questions:

- What conditions place the greatest burden on patients when trying to effectively manage care, and possible solutions to lessen burden?
- What are your thoughts about new ways of providing health care to increase optimal health functioning?
- What are your concerns about potential harm and benefits of treatment options?
- What are your thoughts about the most effective ways to share information and obtain patient input on research the daily lives of patients?
- What strategies/approaches would be most effective for translating health care information into real world settings?
- What ideas do you have to improve methods to use to conduct research studies and the extent to which questions and concerns address issues relevant to patients and caregivers?

We were able to identify barriers in rural communities in regard to communication with the healthcare providers. Some patients refuse to leave their metro providers due to fear of inadequate care in their own communities.

Vanessa, Urban/Rural CHA
**Challenges**

There were several challenges related to implementing this community engagement approach (Table 2). Challenges associated with implementing a community health ambassador model to engage families with SCD can be divided into three categories: 1) organizational challenges; 2) community worker challenges; and 3) patient-driven challenges. Organizational challenges were obstacles that prevented or reduced the progression of the CHAs. These challenges included: resource constraints; overcoming medical facility policies; access to medical facilities; technology difficulties at study initiation; challenges with the hiring process resulting from institutional changes; lack of clarity in job description prior to training; and issues of coordinating CHAs in three different regions throughout the state. In many instances, organizational challenges were introduced by academic institutional policies and were beyond the control of both researchers and the CHAs.

Community worker challenges could be described as circumstances surrounding the CHAs that reduced their ability to perform study related activities. These challenges include: time constraints for completing study activities, limited scheduling availability for training sessions, and personal obligations. These community health worker challenges may not be unique to the Tennessee SCD Network. Instead, researchers and community partners seeking to replicate this CHA model for engaging patients in research should consider the challenges identified when implementing our model. There were community health worker challenges that were specific to implementing the CHA model in this SCD PCOR study. These challenges consisted of limited availability of
CHAs with SCD who had episodes of illness or were caregivers of a patient with SCD. In some instances, the ambassadors had to take time off from the project.

Patient-driven challenges included: establishing trust with the CHAs and researchers; apprehension of CHAs to participate due to historical events in research among African Americans; apprehension due to stigma associated with SCD in the African American community; and time constraints for families seeking to engage in research activities.

<table>
<thead>
<tr>
<th>Table 4: Challenges of implementing a Community Health Ambassador training model to engage SCD families</th>
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</thead>
<tbody>
<tr>
<td><strong>Organizational Challenges</strong></td>
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<tr>
<td><strong>Community Worker Challenges</strong></td>
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<tr>
<td><strong>Patient-Driven Challenges</strong></td>
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</table>
Recommendations for Engaging Patients in Patient Centered Research

- **Input from the sickle cell community is critical.** Best practice strategies to engage minority and underrepresented populations in research should begin with recognition that this community and their contributions play a critical role in the scientific process. This recognition also means allowing community members to help steer the direction of the research.

- **One size doesn’t fit all.** Engaging minority populations is not the same as engaging minorities with a specific disease such as SCD (a rare, hidden disease). One successful approach to establishing trust, rapport, and engagement with the sickle cell community is partnering with a disease-specific, community-based organization. For this research project, we partnered with the Sickle Cell Foundation of Tennessee. This organization’s advocacy for health research and enhancing the of care sickle cell consumers led to an organic and mutually beneficial partnership.

- **Foster positive community-researcher relationships.** Community-researcher relationships may fall along a broad continuum, ranging from distant, detached and impersonal to close, collaborative and friendly. For populations like those with SCD, where stigma and barriers to care are prevalent, researchers’ commitment to the community and development of interpersonal relationships is key. Researchers can show their commitment to the community by allowing time to build the relationship. It is also important for researchers to disseminate results to the community toward project completion. The dissemination of results acknowledges the efforts of the community and shows community members that their contribution to research is valuable.

What works for you may work for others:
 Researchers are continually seeking effective strategies for engaging minority and underrepresented communities in health research. Successful strategies to engage minorities with SCD may serve as a template for engaging other hard to reach or underrepresented populations.
• **Expand the role of CHA to Patient Navigators.** Patient navigators are becoming more commonplace in clinical research. It may be beneficial to expand the role of community health workers to a patient navigator role to assist with engaging patients and providing them with resources outside of education.

• **Get patients on the band wagon early on.** Due to the potential reluctance of patients to participate in research, you need to get patients on the band wagon early on and implementing best practice strategies early on. We didn’t know what some of the best practices were so they were implemented later in the project.

• **Find ways to keep the momentum going.** If your research is ongoing and takes place over an extending period, it was important to keep patients engaged and interest levels high. You may need to elicit ideas from Community Health Ambassadors and members of the sickle cell community.

• **Medical students should be educated on sickle cell disease.** As indicated in the focus group data, patients often have difficulties communicating with healthcare providers and receiving patient-centered care.

• **Expand the train the trainer model to healthcare providers.** Providers who care for patients with SCD have an opportunity to educate medical providers on caring for patients with SCD. For this to occur, providers outside of hematology would need to be open to receiving training from hematologists and other providers in sickle cell care. Trained providers could then return to their home clinics and offer training to their staff.

**Engage multiple disciplines in sickle cell awareness (pharmacists, social workers).** Care for patients with sickle cell disease does not end with hematologists. Like most patients with a chronic illness, SCD patients receive from providers across disciplines. For this reason, it is important to provide education and
awareness in within and outside of medical disciplines.

Most rural and urban families affected SCD have no systematic way to engage in, or lend their expertise to, patient-centered outcomes research. A statewide network of patient partners, community stakeholders, researchers, and medical professionals will ultimately increase the standard of care for patients, and provide valuable insight for sickle cell disease research. The opportunity to create the underpinnings for coordinated patient-centered education and linking of individuals living with SCD and their caregivers, as well as SCD stakeholders throughout the state of TN holds promise for developing a scalable PCOR process model for replication and implementation in other states the success enabling other states with rare disease populations to emulate this model.

Community-engaged approaches have increased potential for inclusion of underrepresented populations with a chronic disease in clinical health research. The presented study showed that use of a community health ambassador training model is an effective mechanism for recruiting, engaging, and retaining sickle cell disease patients and their families as partners in Patient Centered Outcomes Research. Incorporating a community-based organization as a clearinghouse for coordinated communication between the research stakeholders and community was critical to facilitating acceptance of the ambassador among the sickle cell disease community. This model could serve as a scalable model for replication and implementation in other Southern states. Researchers seeking to replicate this training model to increase participation among underrepresented populations clinical research should consider collaborating with a community based organization as an equal partner.
References


Appendix

Meet the Tennessee Sickle Cell Disease Network
Community Health Ambassadors

I decided to participate in the project as a Community Health Ambassador because I wanted to be a "fisherman of men" (women, & children) affected by sickle cell disease, who needed to be brought into a circle where they could be connected with the right people and necessary resources that would enable them to have a better quality of life while living with SCD. During the course of this project, I enjoyed meeting people from all walks of life and ethnic groups and educating them on the importance of understanding their disease and why practicing preventive care and behaviors is fundamental to enabling them to have control over their disease. After a patient meets with a SCD Community Health Ambassador, I hope they gain a sense of empowerment and are ready and equipped to not only fight, but WIN the battle against sickle cell disease.

Janice Reed, Local CHA

Working as a CHA has been a very rewarding and educational experience. I was very humbled to interact with the patients, while learning some of the struggles they have faced in their search for medical care for their illness, which I have learned, can be quite the chore from the perspectives of actual coverage, access, knowledge of how to treat an adult, & affordability. I was further moved at the great length they have had to go to seek information on ways they could manage their medical care to avoid a crisis. It was very easy for me to want to participate in this program because for the past eight years, I have been privileged to work on other projects that have been implemented by Vanderbilt, via Dr. Murry. One of the things that I liked most about participating in this research was how much the patients knew about their medical care and what worked best for them. Some patients carried information with them at all times in case they had a crisis and were not able to speak for themselves. Most of them had done much research concerning their type of SCD as well as the most effective treatment for them. The objective was to educate and train those individuals affected with SCD about treatments and sources to obtain information concerning the disease. The patients were very receptive and had lots of input on gathering information. I hope the patients gained additional knowledge as well other sources of information that is available to them. I believe that the objective of the project has been met. Yet, there is absolutely more that can be done as a result of the findings. This program can be duplicated and bring even more communities can their benefit which can be lifesaving. This program as well as this manual are effective mechanisms to share with other states, and can be effective in helping other states provide useful tools for individuals with SCD.
It was a pleasured serving as Community Health Ambassador. Although I work in a sickle cell clinic, I learned a lot by conducting the research activities. The focus group meetings for rural participants in Tennessee yielded the highest positive results for this two-year study program. Consumers were able to verbalize their concerns when county resources were unavailable and how to effectively negotiate better treatment options. Results revealed how improved communications could be implemented to help rural practitioners become knowledgeable with techniques for improved care and follow-up. Due to limited exposure for some providers in rural Tennessee; consumers lacked the will and desire to confront myths about sickle cell disease. Often times, they were forced to seek immediate assistance from outside their home community. While others simply abandoned an opportunity to confront biases/challenges in their respective treatment centers. Once assembled however, I concluded the participants were eager to “share” similar experiences and presumed their collective voices would make a difference.

Vanessa Steele, Local CHA

Hi, I’m Alexis, and I have Sickle Thalassemia Beta Zero. Although it sounds like a Greek organization, it is far from that. Sickle Thalassemia Beta Zero is considered a milder form of Sickle Cell disease; however, the pain crises are just as painful as the other forms. As a child, I learned early on that I had to understand the details of my Sickle Cell disease to ensure I could thoroughly articulate my situation to anyone at any time. I was blessed to have a mother as a nurse and direct access to the medical community. This access allowed me to learn firsthand about my form of Sickle Cell disease and empowered me with the information to communicate effectively when in need of care. Thus, my labor of love is self-advocacy and empowerment for those living with Sickle Cell disease. I am passionate about helping patients and families learn how to live with joy with the disease. Everyone deserves to live with joy!

Alexis Gorden, Regional CHA
In all, serving as a Local Ambassador during the PCORI Research Project was a truly a great experience. I decided to participate because, simply put, I want to give back to the Sickle Cell Community. I know firsthand how life with this illness can take a toll on one's self. One thing I've always made a point to do, though, is make sure I didn't miss any of my doctors' appointments. I honestly couldn't imagine life without a medical home. Therefore, I just felt an obligation to the Sickle Cell Community to help identify those consumers who live in both urban and rural areas who need a medical home. I really enjoyed gaining the research data and making a difference in the community. Interacting with the patients, hearing their concerns, and actually seeing where I can help them was very gratifying in itself. I know it may be weird, but I also enjoyed the planning/strategic meetings. Hearing other team members’ wonderful ideas was very inspiring and made me excited about the work we had ahead of us. I really hope the work we accomplished within this project will help those consumers we reached, providers as well, see the importance of having a medical home. I hope the providers understand the importance of hearing out their patients concerns when it comes to treating their Sickle Cell. This was a great experience and I really learned a lot from all those on the team. Now I'm inspired to participate in more research grants so that I can give back to the Sickle Cell Consumers.

Trevor Thompson entered this project with a patient and advocate perspective. He was not only motivated by his will to live life to the fullest with sickle cell disease but to also empower other sickle cell consumers to live a full and prosperous life. Although his personal, educational, and professional experiences made Trevor an expert sickle cell disease, his participation in a research study as a Community Health Ambassador reflected an opportunity to become a credentialed health educator in the area of sickle cell disease and patient-centered outcomes research. For Trevor, this was of the utmost importance, as it meant being able to share his firsthand expertise as a patient, advocate, educator, and researcher with clinical staff and researchers. Participating in the PCORI project was also an opportunity to further the short-term and long-term benefits for patients and families impacted by sickle cell disease. Trevor spent countless hours advocating on behalf of sickle cell consumers both as a community organizer and as a community partner in research. The PCORI project allowed him to engage other sickle cell consumers who wanted to make a difference in sickle cell through research. Trevor personally selected the Community Health Ambassadors to join him on his journey in Patient Centered Outcomes Research. The experiences each ambassador received are result of Trevor’s vision for helping patients and families. Although Trevor is no longer physically with us, the patients, families, ambassadors, and researchers will continue his legacy and journey through works such as the Tennessee Sickle Cell Disease Network project.
Research Presentations
Community Engagement Studio
Community Health Ambassadors Present Sickle Cell Research 101 in Rural Community
Data from Focus Groups

Where do you receive information about managing your sickle cell disease?

1.1 Health provider: 17
1.2 Experience: 21
1.3 Internet: 14
1.4 Peers/family: 4
1.5 Other people with sickle cell: 7

Satisfaction with information received to self-manage the disease

2.1 Satisfied: 5
2.2 Unsatisfied: 6
2.3 Ways information could be improved: 12
2.4 How uses/appplies information received: 8
2.5 Method would like to receive information: 12
3.1.1 Information about the types of sickle cell disease, symptoms of sickle disease, etc.

3.1.2 Information about genetics/inheritance

3.2 Information about treatment

3.3 Specificity of Information

4.1 General support comment

4.1.1 Spouse/partner

4.1.2 Parent/grandparent

4.1.3 Friend/roommate

4.1.4 Children

4.3.1 Faith/Religion

4.3.2 Accompaniment in healthcare settings

4.3.3 Physical care

4.3.4 Emotional care
5.1.1 Health reminders
5.1.2 Environment alerts
5.1.3 Crisis alerts
5.2 Communication with others
5.3.1 Information about sickle cell disease
5.3.2 Information for health providers
5.3.3 Daily log
5.4 Use of app
5.4.1 Personal use of app
5.4.2 Family/caregiver use of app
5.5 Frequency of use

6.1.1 Patient level
6.1.2 App level
6.1.3 Provider level
6.2.1 Patient level
6.2.2 App level
6.2.3 Provider level
SSD Challenges

- 7.1.1 Providers’ lack of knowledge about the disease: 55
- 7.1.2 Provider disrespect/dismissiveness: 37
- 7.1.3 Insufficient care: 60
- 7.2.1 Changes/strain in relationships: 7
- 7.2.2 Ability to complete everyday activities: 11
- 7.2.3 Self care or lack thereof: 37
- 7.3 Prognosis: 6

Additional Discussion

- 8 Questions: 22
- 9 Relating: 39
- 10 Non app-related suggestions: 24
- 11 Discussion of existing app: 4
## Table of Themes and Categories

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<thead>
<tr>
<th>Theme</th>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Methods for receiving information about managing SCD</td>
<td>Health provider</td>
<td>Participant receives information from a health provider.</td>
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<tr>
<td></td>
<td>Experience</td>
<td>Participant learns information about managing sickle cell disease through personal experience over time or through trial of new activities/methods.</td>
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<tr>
<td></td>
<td>Internet</td>
<td>Participant receives information online.</td>
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<tr>
<td></td>
<td>Peers/family</td>
<td>Participant receives information from other people.</td>
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<tr>
<td>Satisfaction with information received to self-manage SCD</td>
<td>Other people with sickle cell</td>
<td>Participant receives information from a person affected by sickle cell disease.</td>
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<td>Satisfied</td>
<td>Discussion centers on level of satisfaction with information received for self-management of SCD. Participant is satisfied with the information they have received to self-manage their disease. For example, due to level of experience with SCD, satisfied until the disease is unmanageable.</td>
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<tr>
<td></td>
<td>Unsatisfied</td>
<td>Participant is unsatisfied with the information they have received to self-manage their disease. For example, lack of new information, lack of credibility.</td>
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<tr>
<td></td>
<td>Ways information could be improved</td>
<td>Discusses ways in which information received could be improved.</td>
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<tr>
<td></td>
<td>How uses/applies information received</td>
<td>Discusses ways that information received is or can be used/applied.</td>
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<tr>
<td></td>
<td>Method would like to receive information</td>
<td>Discusses methods in which s/he would like to receive information.</td>
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<tr>
<td>Desired information</td>
<td>Information about the disease itself</td>
<td>Participant expresses interest or lack of knowledge in information about their disease.</td>
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<td></td>
<td>Information about the types of sickle cell disease, symptoms of sickle disease, etc.</td>
<td>Participant expresses interest or lack of knowledge in information about the different types of sickle cell disease, symptoms of sickle cell disease, etc.</td>
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<tr>
<td></td>
<td>Information about genetics/inheritance</td>
<td>Participant expresses interest or lack of knowledge in information about hereditary issues of sickle cell disease.</td>
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<tr>
<td></td>
<td>Information about treatment</td>
<td>Participant expresses interest or lack of knowledge in information regarding treatment (clinical trials, treatment methods, medication) of sickle cell disease.</td>
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<tr>
<td></td>
<td>Specificity of Information</td>
<td>Desire for information more specific to a certain population.</td>
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<tr>
<td></td>
<td>Other</td>
<td>Other types of information desired that cannot be categorized above.</td>
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<tr>
<td>Support</td>
<td>Support person</td>
<td>Discussion centers on who helps participant manage her/his disease. Participant mentions a specific person who supports them in managing their sickle cell disease.</td>
</tr>
<tr>
<td></td>
<td>Spouse/partner</td>
<td>Participant mentions a husband, wife, boyfriend, or girlfriend who helps them manage their sickle cell disease.</td>
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<tr>
<td></td>
<td>Parent/grandparent</td>
<td>Participant mentions a parent or grandparent who helps them manage their sickle cell disease.</td>
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<tr>
<td></td>
<td>Friend/roommate</td>
<td>Participant mentions a friend or roommate who helps them manage their sickle cell disease.</td>
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<td></td>
<td>Children</td>
<td>Participant mentions that their children help them manage their sickle cell disease.</td>
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<td></td>
<td>Methods of support</td>
<td>Participant mentions a way in which they are supported in managing their sickle cell disease.</td>
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<td></td>
<td>Faith/Religion</td>
<td>Participant mentions role of faith in management of their sickle cell disease.</td>
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<td></td>
<td>Accompaniment in healthcare settings</td>
<td>Participant mentions support from another person in a medical setting through advocacy or presence at health center.</td>
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<tr>
<td></td>
<td>Physical care</td>
<td>Participant mentions support from another person through physical care such as administering medicine, performing massages, applying heat, etc.</td>
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<tr>
<td>Emotional care</td>
<td>Participant mentions support from another person through emotional care such as support, reminders to take medication, and provision of information.</td>
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<tr>
<td><strong>App Features</strong></td>
<td><strong>Participant describes desirable features and usage of an app to manage SCD</strong>&lt;br&gt;Participant describes alertsnotifcations they would like to receive through the app.</td>
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<tr>
<td>Alerts</td>
<td>Participant mentions health reminders regarding medication, pain management strategies, etc.</td>
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<tr>
<td>Health reminders</td>
<td>Participant mentions health reminders regarding medication, pain management strategies, etc.</td>
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<tr>
<td>Environment alerts</td>
<td>Participant mentions alerts regarding weather changes and other environmental factors that might affect sickle cell disease.</td>
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<tr>
<td>Crisis alerts</td>
<td>Participant mentions the app’s role in a potential crisis/emergency situation.</td>
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<tr>
<td>Communication with others</td>
<td>Participant mentions communication possibilities with parents, health providers, etc.</td>
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<tr>
<td>Information on app</td>
<td>Participant mentions specific information the app should have. Information regarding sickle cell disease, medications, pain management tips, etc.</td>
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</tr>
<tr>
<td>Information about sickle cell disease</td>
<td>Information regarding patient information (history of condition, prescriptions, specific needs) as well as contact information for family members, previous health providers, and advocates.</td>
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<tr>
<td>Information for health providers</td>
<td>Participant mentions a type of health log in which they can record mood, pain level, diet, etc.</td>
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<tr>
<td>Daily log</td>
<td>Discussion centers on barriers that would interfere with app usage and features that would facilitate use.</td>
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<tr>
<td>Use of app</td>
<td>Discussion centers on factors that would interfere with app usage.</td>
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<tr>
<td>Personal use of app</td>
<td>Participant comments specifically on whether or not they would use the app.</td>
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<tr>
<td>Family/caregiver use of app</td>
<td>Participant comments specifically on whether or not their family members or caregivers would use the app.</td>
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<tr>
<td><strong>Barriers and Facilitators to the use of app</strong></td>
<td>Participant comments on predicted frequency of use of app.</td>
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<td>Frequency of use</td>
<td>Discussion centers on barriers that would interfere with app usage and features that would facilitate use.</td>
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<tr>
<td>Barriers to the use of app</td>
<td>Discussion centers on factors that would interfere with app usage.</td>
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<tr>
<td>Patient level</td>
<td>Discussion centers on patient-level barriers that would interfere with app usage.</td>
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<td>App level</td>
<td>Discussion centers on app-level barriers that would interfere with app usage.</td>
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<td>Provider level</td>
<td>Discussion centers on provider-level barriers that would interfere with app usage.</td>
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<td>Facilitators to the use of app</td>
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<tr>
<td>Provider level</td>
<td>Discussion centers on provider-level factors that would facilitate usage.</td>
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<td><strong>SCD challenges</strong></td>
<td>Participant discusses other challenges they face with sickle cell disease.</td>
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<td>Frustrations related to medical care</td>
<td>Discusses frustrations pertaining to medical treatment of SCD.</td>
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<td>Providers’ lack of knowledge about the disease</td>
<td>Participant mentions frustration regarding health providers who do not have sufficient knowledge regarding sickle cell disease.</td>
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<tr>
<td>Provider disrespect/dismissiveness</td>
<td>Participant mentions negative experiences due to a provider’s dismissing/disrespecting the participant.</td>
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<td>Insufficient care</td>
<td>Participant mentions insufficient care at clinics or hospitals related to their condition.</td>
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<td>Frustrations related to everyday life</td>
<td>Everyday frustrations related to SCD.</td>
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<tr>
<td>Changes/strain in relationships</td>
<td>Participant mentions strain/changes within relationships related to their diagnosis.</td>
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<tr>
<td>Ability to complete everyday activities</td>
<td>Participant comments on the effect of their diagnosis on their ability to participate in normal activities.</td>
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<tr>
<td>Self-care or lack thereof</td>
<td>Discussion centers on participants’ self-care or lack of self-care.</td>
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<tr>
<td>Prognosis</td>
<td>How participant’s prognosis has affected how s/he lives/quality of life.</td>
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</tbody>
</table>
Contacts

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901-552-4267 / 888-695-0006
PCORI – TN Sickle Cell Disease Network Cell Network Project


Developed & Implemented by:
Dr. Velma McBride Murry
Lois Autrey Betts Chair, Education and Human Development
We are pleased that you will be working with Vanderbilt University (VU) - TN Sickle Cell Disease Network Project. In accepting the position, you will become an employee of Vanderbilt University. This document describes the job you will be expected to perform and some of Vanderbilt University’s policies on confidentiality and employment for your position. To be sure you understand the relationship between you and Vanderbilt University, please read this document carefully, initial and date each page (where indicated), sign it (where indicated on the last page), and return it to designated PCORI TN Sickle Cell Disease Network Project staff. If you have any questions, please contact Trevor Thompson (sicklecelltn@gmail.com) or Janice Reed (janice@reed-realestate.com)

Community Ambassador’s Charge:

1) To serve as a participating member of the PCORI Sickle Cell Disease Project
2) To identify and recruit individuals and families in your area who are affected by Sickle Cell Disease
3) To serve as a liaison between TN Sickle Cell Disease Network Project and Vanderbilt Medical Center and the recruited families/individuals affected with sickle cell disease.

RECRUITMENT: A total of 400 TN individual/families affected with sickle cell will be recruited to participate in the TN Sickle Cell Disease Network Project. To recruit families three Regional Community Ambassadors and their team of two Local Community Ambassadors will develop strategies and procedures to identify and enroll individuals and families affected with sickle cell disease in the project. Two teams will recruit 133 participants and one team will recruit 134 families to reach the 400 recruitment target goal.
During your employment, you will be expected to adhere to the requirements and policies set out in this document.

1. **PREREQUISITES** - By reading and signing this document you are certifying that you:
   - Have the means to make phone calls, home visits and other community contacts on behalf of Vanderbilt University PCORI TN Sickle Cell Disease Network Project
   - Have an awareness of your community and have connections with community leaders and resources to link you with potential participants to enroll in the project
   - Can readably be contacted by telephone, text messaging, and email
   - Are available for scheduled conference calls and in-person meetings
   - Have the time to commit to working with the PCORI TN Sickle Cell Disease Network Project as a Community Ambassador, which includes being available and being able to respond to requests within three business days
   - Are well connected and respected in your community

2. **RESPONSIBILITIES AND DUTIES:** As a Community Ambassador, you are being asked to perform the following tasks and related activities as they are assigned to you Principal Investigators of the TN Sickle Cell Disease Network Disease Project (Drs. Michael DeBaun, MD, and Velma McBride Murry, PhD), the Director of Sickle Cell Foundation of TN (Mr. Trevor Thompson), and Lead Community Ambassador (Mrs. Janice Reed).
   - Recruit families for the PCORI TN Sickle Cell Disease Network Project (TN-SCDN) Project
   - Attend community activities that may aid in identifying, recruiting, and enrolling participants
   - Make home visits and phone calls to families on behalf of PCORI TN-SCDN
   - Document and track activities in a timely manner
   - Submit all required reports in a timely manner
   - Work closely with Lead Community Ambassador, Director of SCD Foundation of TN, other Community Ambassadors in TN to provide weekly updates on progress
- Attend weekly teleconference meetings
- Select individuals and families enrolled in the project from your region to participate in involvement of participants in various research related activities as determined by members of the Vanderbilt University Research Team, which includes participating in focus groups to provide input on how to more effectively address the needs of families affected by sickle cell; how to effectively engage individuals affected by sickle cell in research and clinical trials.
- Coordinate transportation and other ancillary services that will facilitate individuals and families participating in activities related to the PCORI TN-SCDN project
- Adhere to Vanderbilt University and PCORI TN-SCDN Project rules and guidelines
- Perform other duties as assigned
- Advocate on behalf of PCORI TN-SCDN Project with community leaders, stakeholders, and other regional and local organizations

3. PREPARING TO LAUNCH YOUR ROLE AS COMMUNITY AMBASSADOR:
   ✓ Before you meet with various community leaders, stakeholders, potential individuals/families ---
   - Familiarize yourself with the project. Break it down to the following key questions that you should be able to answer if asked by a potential family:
     1. What is this project?
     2. What will be required of my family or me if I/we enroll?
     3. What will be required of me to participate?
     4. When will this project begin?
     5. How long will the project last?
     6. Why would I want to participate in this project?
     7. You mentioned that I will have a chance to provide feedback and input to the members of the project about how to best serve families affected by sickle cell disease. What will I have to do?
     8. Where will the sessions be held?
     9. When will they be held?
    10. Will all of my family have to attend?
    11. How will I get to the place?
    12. How much time will be required of my family?
✓ **Read, Read and Read** again the recruitment script! *(See Recruitment Script)*. Redo/revise script as needed to convey appropriate information in an understandable manner. Know the project information enough to convey it in a conversational tone. When you share information about the project try not to read the script!

✓ **Practice makes perfect**: Make a few practice in-person or telephone calls to friends, family members (people who are not in the recruitment pool), other Community Ambassadors, to obtain feedback on your presentation of information about the project before your first visit.

✓ **Tailor your presentation**: Revise the recruitment script and tailor it to fit the outreach setting. For example, be prepared to share information using a different approach if you are visiting with church officials, community health agency, school system, on giving a public announcement on a local radio station, versus going into a family’s home to discuss the project.

✓ **During the visit**. Provide an overview of the project, why it is important, your role, and purpose of your visit. Please use appropriate form to record information from the visit. Use the contact information form to record the family the following information: Name of individual/individuals who is affected by sickle cell, names of primary caregivers, if appropriate, address, telephone/cell number, email, and any other social media.

**RECRUITING THROUGH PHONE CALLS:**

4. **MAKING PHONE CALLS**:

✓ Calling families is one of the most effective ways we use to recruit families, but it can also be intimidating. Many people would much prefer face-to- face encounters, but time constraints limit our ability to consistently do this. In an effort to make your phone calling experience more successful, we have put together some suggestions that may give you positive results:

  o Call families you know first, this will give you more practice with your delivery.
Vary your calling times; call on weekends, mornings and evenings. Note: Try not to call after 10:00 p.m. or before 10:00 a.m. unless an individual/ adult family member gives you permission to do so.

Record and or update the contact logs as you make phone calls.

Be pleasant, thorough and professional on the phone no matter what the mood of the person called. Try to find a common bond with the family.

Stay organized, separate call records by results, such as callbacks, disconnections, ineligibles, or other phone problems.

If a family refuses, ask for the reason, do not pressure them if they don’t feel comfortable revealing their reason(s). Note reason on the contact log.

Once five phone calls have been made to a family and have not produced any results such as, no one ever answers phone, someone keeps telling you to call back, or the phone always goes straight to voice mail, etc. then you should attempt 3 home visits. If neither method yields results, consider this family as being “non-responsive,” note procedures in contact logs.

When families have agreed to participate, all Community Ambassadors will schedule an appointment to visit the individual/family in their home to officially obtain information to add to the database. Local Community Ambassadors will submit enrollment materials to their Regional Community Ambassador, who will enter all enrollment information into the project’s REDCAP account.
RECRUITING THROUGH HOME VISITS

5. **Home Visits** - While phone calls can be utilized as a recruitment method to provide families with information about the project and sign them up for participation, if the family is unreachable via phone, then a personal visit to a family’s home without having spoken to them prior may be necessary.

Each Region is responsible for recruiting 133 or 134 individuals/families affected by sickle cell disease. Phone calls take about 20 minutes to complete and home visits generally take about 40 minutes to complete. If a family declines participation, note their decision on the contact log and send that information to Lead Community Ambassador with your weekly mailings.

The project will last until December 2016, so families will need to be retained in the project during that time. We have several other activities that families will have the opportunity to participate. During the family retention phase of the project, Community Ambassadors duties will include:

- Developing neighborhood contact procedures (visiting home addresses, utilizing neighbors as contacts, etc.) to find contact information to ensure that you have updated information on the families
- Updating family information in REDCAP account and informing the Lead Community Ambassador of any changes in family records

6. **COMMUNITY AMBASSADORS EXTRAS**
Sometimes, situations in recruitment arise that may require special handling. Although all situations cannot be addressed, hopefully this list will help with some of the most common ones. Please remember that Vanderbilt University PCORI TN-SCDN based staff is always available to answer your questions.
There has to be at least one individual in the household who has been diagnosed with sickle cell disease.

When the targeted person in the recruitment is an individual under age 18 years old, the primary caregiver needs to be involved and can be a father, mother, grandmother, aunt, etc. The only requirement is that the target person(s) with sickle cell must be living with them and must be proficient in English.

All family members, including both caregivers, are allowed to enroll in the project.

Each family/individual who enrolls, regardless of number of members in the family, will be counted as one enrollee.

No one other than the Community Ambassadors and members of the Vanderbilt research team will have access to participants’ information.

7. PAYMENT FOR SERVICES -

Community Ambassadors will be compensated for all work activities, including recruiting and enrolling individuals/families affected by sickle cell disease, arranging for participants to attend various research related events/activities.

Payment Structure

Local Community Ambassadors will receive $20 for each family recruited and enrolled in the TN SCDN. A list of recruited families will be submitted weekly to Regional Community Ambassadors. Total enrollment for each month must be submitted to the Regional Community Ambassador no later 24 hours before the last business day of each month. Payment will be remitted monthly and based on number of enrollees submitted to and confirmed by the Regional Community Ambassador.

Regional Ambassadors are expected to recruit participants as well as supervise Local Community Ambassadors work efforts, contributing 6-8 hours per month during the grant funding cycle at a rate of $25.00 per hour.
Information to submit to Director of Sickle Cell Disease Foundation of TN and the Lead Community Ambassador

WEEKLY: Each week Regional Ambassadors will submit summary of all recruitment activities for their respective region for each Local Community Ambassador and Regional Community Ambassador’s recruitment efforts.

MONTHLY: Lead Community Ambassador and Director of SCFT will send copies of all signed completed recruitment materials via regular mail or scanned electronic copy to Dr. Velma McBride Murry, and a member of the research team will file forms in secure location at Vanderbilt University.

In addition, a monthly recruitment progress report will be submitted for each respective region, reflecting enrollment for each participant completed by each Local Community Ambassadors.

Finally, Regional Community Ambassadors will submit an invoice for payment describing their own project activities and number of hours. This information will be submitted on the last business day of each month and will be reviewed and confirmed by the Lead Community Ambassador and The Director of Sickle Cell Disease Foundation of TN. The Director of Sickle Cell Disease Foundation of TN will submit this report and payroll recommendations to Dr. Velma McBride Murry for review and approval for monthly payroll.

REPORTING RECRUITMENT ACTIVITIES:
Regional and Local Community Ambassadors will record recruitment activities on the paper family contact logs. In addition, every Friday (see important dates chart for specific dates), each Local Community Ambassador is expected to email a report to Regional Community Ambassador, who will in turn email a combined report for their respective region to the Lead Community Ambassador, including the following information:

1. Community Ambassador’s Name
2. Community Ambassador’s County
3. Number of individuals/families enrolled since last report (with Family ID #)
4. Number of individuals/families declined since last report (with Family ID #)
5. Total number of individuals/families enrolled
6. Total number of individuals/families declined

Payment from Vanderbilt University will be placed in the mail on Vanderbilt payday (specified in “Vanderbilt Timesheet submission” chart and should arrive within 2 weeks (the normal delivery time).

A successful recruitment one in which your contact logs indicate the number of individuals/families you have completed in-take information. Once your paperwork is reviewed and approved by Dr. Velma McBride Murry, your payroll will be submitted for payment.

8. **TRAINING/MEETINGS** – A weekly teleconference meeting will be scheduled at 3:30 p.m. on Fridays. All Community Ambassadors are expected to join the teleconference calls. A standing meeting and time will be established during training. The meeting will be lead and organized by the Director of SCFT and Lead Community Ambassador.

9. **MATERIALS** - Throughout the period of your work on the project, you will be provided with supplies necessary to complete your work on this project. At the completion of the project, or at the termination of your employment, you must return all equipment and all unused material, which were supplied, to you.

10. **POLICY VIOLATIONS** - All Vanderbilt University PCORI SCD-TN Project employees will receive a copy of the policies and expectations of the position. Any infractions of these policies and expectations will be documented and become part of the employee’s personnel file. Employees will be terminated after three documented infractions or one breach of confidentiality.
These infractions include, but are not limited to the following:

a) Failure to complete work in accordance with the schedule specified, or failure to maintain the number of hours you have agreed to be available for visits each week in the absence of a valid excuse.

b) Inadequate justification for any work-related hours claimed.

c) Services not performed to the satisfaction of the project administration.

d) Validation checks, supervisory visits, or editing indicate that work is not being performed satisfactorily.

e) Failure to contact relevant Research Staff when problems arise.

f) Failure to report to work as assigned.

11. RESIGNATION - If you decide to terminate your employment with Vanderbilt University we require written notice of your termination 2 weeks before the date on which you plan to stop work.

12. Staff finds it necessary to terminate your employment, they will do so by written notice to you. Possible reasons for immediate termination include, but not limited to:

   o Violating the “Staff Confidentiality Agreement”
   o Submitting falsified work.
   o Dismissal during probationary period.
   o Exhibiting conduct that adversely affects PCORI SCD-TN Project /or Vanderbilt University as determined by the Project Research Staff.
   o Failure to provide full and pertinent information on your application that is relevant to your effectiveness and/or eligibility for the assignment.
   o Any determination by the Director of Sickle Cell Disease Foundation of TN and/or Lead Community Ambassador that it is in the best interest of the Project or VU to discontinue your employment.
13. STAFF CONFIDENTIALITY AGREEMENT

**Statement of Policy** – PCORI Engagement Award, SCD-TN and Vanderbilt University are firmly committed to the protection of the confidentiality of individual participants and all data obtained through Vanderbilt University research. This principle holds before AND after any specific guarantee of confidentiality is given at the time of interview.

It is the policy of all research staff of the PCORI Engagement Award, SCD-TN to protect the identity of each participant. All information that links a specific participant to involvement in the PCORI Engagement Award, SCD-TN Project should be held confidential. This commitment to confidentiality prohibits all Community Ambassadors from discussing information regarding project participants with anyone other than members of the PCORI Engagement Award, SCD-TN project team.

14. Procedures for Maintaining Confidentiality

1. All PCORI Engagement Award, SCD-TN employees must agree to and maintain the “Pledge of Confidentiality”. This pledge may be superseded by another assurance for a particular project.

2. Maintaining confidentiality extends into the future; it is not limited to the period of the time that data collection or recruitment is being carried out. Community Ambassadors shall exercise utmost caution to prevent access by others of participant information in their possession.
**Pledge of Confidentiality** - I hereby certify that I have carefully read, and will cooperate fully, with the above procedures on confidentiality. I will keep confidential all information arising from surveys concerning individual respondents to which I gain access. I will not discuss, disclose, disseminate, or provide access to data or identifiers except as authorized by PCORI Engagement Award, SCD-TN for a particular contact. I understand that violation of the privacy rights of individuals through such unauthorized discussion, disclosure, dissemination, or access may make me subject to criminal or civil penalties, as well as termination. I give my personal pledge that I shall abide by this agreement of confidentiality.

____________    ___ / ___ / ___
Initial                   Date

**SIGNATURE** - I have read this document; I understand the job description and policies outlined; I meet the prerequisites set out in paragraph 1 above; I agree to the procedures and policies described in this document.

Employee Name (Print) ____________________________________

Signature _______________________________________________

Date _________________________________________________
General Employee Policies

Community Ambassadors Meetings
Community Ambassadors (CAs) are expected to attend weekly teleconference meetings and other project related meetings that are held throughout the grant cycle. During these meetings, Community Ambassadors are free to discuss any concerns or problems that arise and to help create solutions to those problems. If any Community Ambassador wants or needs to talk to Vanderbilt PCORI Engagement Award, SCD-TN staff members, at any time, please do not wait until a regularly scheduled staff meeting. We want your feedback and its better when information is fresh on your mind.

How are staff evaluated?
The Director of Sickle Cell Foundation of TN and Lead Community Ambassador will be responsible for ongoing monitoring of each Regional Community Ambassador and will seek feedback from each Regional Community Ambassador on work performance of each Local Community Ambassador. Feedback and monitoring will focus on availability, accuracy and timeliness of paperwork, meeting recruitment milestones, assistance with other community engagement activities, etc. Written feedback will be submitted to Community Ambassadors every four months.

Communication
Communication is essential for the proper operation of the PCORI Engagement Award, SCD-TN Project. Please communicate all concerns and project issues to the Lead Community Ambassador, as the first point of contact, followed by Director of Sickle Cell Foundation of TN, and if necessary, please contact Drs. McBride Murry or DeBaun directly.
Community Ambassador Information Sheet

NAME:
___________________________________________________________________________

STREET ADDRESS:
________________________________________________________________

MAILING ADDRESS:
_______________________________________________________________

CITY: _____________________ STATE: __________________ ZIP: _____________

HOME PHONE: _____________________ CELL PHONE: ______________________

PLACE OF EMPLOYMENT:
_________________________________________________________

WORK PHONE: ______________________ FAX NUMBER: __________________________

E-MAIL ADDRESS: ____________________________________________________

BEST TIME TO CALL: ________________________________