PCOR

PATIENT-CENTERED OUTCOMES RESEARCH TRAINING MANUAL:

Helping researchers initiate and maintain patient-engaged research teams

Brought to you by the University of Washington Department of Family Medicine UW DFM in collaboration with the Cystic Fibrosis Reproductive and Sexual Health Collaborative, Cystic Fibrosis Foundation and Cystic Fibrosis Research Institute. This work was funded by the Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington Program Award (10569-UWASH). The content is solely the responsibility of the authors and does not necessarily represent the official views of PCORI.

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Cystic Fibrosis Reproductive and Sexual Health Collaborati

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A Training Manual for Patient-Centered Outcomes Research

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Writing

This guide was created through a collaboration between the University of Washington, Cystic Fibrosis Foundation, Cystic Fibrosis Research Institute, clinicians, researchers, patients, and caregivers from the Cystic Fibrosis (CF) community. The first draft of this training manual was written by Emily Godfrey, Molly Pam, and Brittany Rattiliff. Drafts were reviewed and input was provided by Morhaf Al Achkar, Molly Ruben, and our CF PCOR Community Advisory Board throughout the development process.

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Abbreviations

CAB: Community Advisory Board
CF: Cystic Fibrosis
CFF: Cystic Fibrosis Foundation
CFReSHC: Cystic Fibrosis Reproductive and Sexual Health Collaborative
CFRI: Cystic Fibrosis Research Institute
PCOR: Patient-Centered Outcomes Research
PCORI: Patient-Centered Outcomes Research Institute

Glossary

Champion: Individuals who advocate for and support implementing a new program, policy, or process. Effective champions are generally respected members of the institution and research team, have some authority to direct resources to support implementation, and possess a personal commitment and passion for seeing the innovation fully implemented.

Cystic Fibrosis - Cystic fibrosis is a progressive, genetic disease characterized by sticky mucus that damages the lungs and digestive system, causes lung infections, and limits the ability to breathe over time.

Engagement: Performing or recruiting others to accept an authentically valued role in the research process.

Patient/parent/caregiver-partners – Individuals who are directly affected by CF. They may have CF or care for another person who lives with CF. For the purposes of this training manual, we will use partners to represent all non-researcher stakeholders types.

Project Lead – The lead researcher and primary contact for the research project. Usually, this person is employed by an academic institution, but partners can also be Project Leads. In this manual instead of using the term "Principal Investigator" (PI), we use "Project Lead" to denote the person leading the project because it is a more widely understood term by community and other stakeholders.

Stakeholder – Stakeholders generally include patients, caregivers, clinicians, researchers, community advocates, and other community members.

A. BACKGROUND

A.1 Overview

Medical treatments have led to increasingly longer life expectancies for people with cystic fibrosis (CF), increasing the need to address emerging and unique health issues voiced by patients with CF. As a multi-organ disease, treatment for CF is complex, often requiring the use of multiple medications daily. In the clinical encounter, specialized medical care often overshadows other critical components related to personal goals of patients. Yet, research shows that attention to the patient voice is imperative for successful shared decision making and improvement in health outcomes. When patients are not equal partners in their own care, psychological chasms can form between patients and healthcare providers potentially affecting adherence to treatments and communication with the care team. In the research setting a similar concept applies. The voice of patients with CF should be seriously considered in prioritizing research questions and agendas to ensure successful implementation of research findings into clinical care. This relationship is deeper than what many patients in the CF community are already doing, which is to inform research by prioritizing research questions, reviewing grants, or participating on safety monitor boards. Engagement is meant to be a long-term commitment with the research team, seeing the research from the development of the research question through dissemination of the study's findings. **Building the capacity of patients, clinicians, and researchers to participate equally in patient-centered outcomes research (PCOR) is essential to creating meaningful partnerships that lead to improved CF care, knowledge, and resources.**

The incredible and recently observed success of the cystic fibrosis transmembrane conductance regulator (CFTR) modulators underscores this need. In a span of just a few years, the experience and lifespan of many patients with CF has changed dramatically, causing patient priorities to shift from simple health and life extension to new lifestyle, career, family planning, and health considerations. In addition to reproductive health questions that correspond with CF patients living longer, healthier lives, there are several examples of other areas of CF care that could benefit from patient engagement from mental health and CF-related diabetes (CFRD) to post-transplant experience and racial disparities in CF care and diagnosis. These areas can all follow the example of female sexual and reproductive health as an example of how to create important research from patient priorities.

Due to their improved health status, many women and pregnancy-capable persons with CF began to contemplate pregnancy and parenthood, but felt they had little information to guide them as to whether it was safe, and when would be the most optimal time to get pregnant. When individuals with CF came together in 2016, they realized they had many unanswered questions related to sexual and reproductive health. Many patients noted they felt their ovulatory cycle was correlated with their respiratory symptoms. Others reported having body image concerns from weight gain on new medications to transplant scars and IV lines. Others wondered about the safety of hormonal contraception or pregnancy, in light of the medications they were taking. Other individuals with CF wondered about parenthood decisions and menopause. This small group of adult individuals with CF came together with multidisciplinary clinicians and researchers to discuss how CF-specific female health concerns had become central questions in their lives. Accordingly, this initial group formed the Cystic Fibrosis Reproductive and Sexual Health Collaborative (CFReSHC) (www.cfreshc.org) which created patient-centered research priorities related to women's health. By 2020, the Cystic Fibrosis Foundation (CFF) Therapeutic Development Network (TDN) created the Women's Health Research Working Group, which includes individuals with CF as key stakeholders.

CFReSHC and the CFF Women's Health Research Working Group demonstrate the benefits of and the rapid pace by which engaging patient/caregiver-partners on research teams can identify research gaps, determine research priorities, and develop infrastructure to move research priorities forward.

Stakeholder engagement on research teams improves the relevance of research, increases stakeholder trust in research and researchers. Engagement enhances mutual learning by stakeholders and researchers about each other, and improves adoption of the research findings. The Training Manual Development Group conducted a survey in 2019 and found that 86% of 170 CF researchers, healthcare providers, patients, and caregivers were interested in learning more about how patients/caregivers could act as key stakeholders on research teams. Survey respondents also mentioned the need to have specific, authoritative guidance for how best to incorporate partners onto research teams; serving as the impetus to create this particular Training Manual.

What we learned when we surveyed the CF Community...

86%

of patients, caregivers, health care providers, researchers and research staff are interested in learning about PCOR

Top three training topics included how to...

Patient/Caregivers

- Openly communicate with researchers
- Build trust with researchers/providers
- Share expertise with researchers

Researchers/Healthcare providers

- Include outcomes that matter to patient/caregivers
- Partner with patient/caregivers
- Select relevant research topics

A.2 Goal

The goal of this Training Manual is to promote patient engagement in the CF community by increasing the number of PCOR research teams and improving the quality of participation of the patients, caregivers and other community stakeholders who are engaging with researchers. This Training Manual aims to do this by providing discrete steps, tools, and resources that teams can take to successfully integrate and maintain partners in CF research.

This document is primarily written for CF researchers and CF health care providers working within CF centers in academic institutions and research funders, such as CFF and CFRI. Because institutional and program environments vary greatly, it is possible that some guidance may not be applicable. However, it is anticipated that individual CF programs will use this Training Manual as a starting point to help ensure successful engagement of new stakeholders onto the research team. It is possible that users may benefit from additional guidance from a qualified and skilled mentor in patient-engagement methodology.

People with CF, their caregivers, and other stakeholders are critical players in this work and in the development of this Training Manual. While this Training Manual is not directed at patients, caregivers, and other stakeholders to initiate PCOR research teams, we believe the patient/caregiver voice is critical to this manual to inform CF researchers and providers about what to know when approaching and interacting with patients/caregivers as authentic partners on research teams. Partners may also wish to reference this Training Manual to educate themselves on the research process, or how to participate on a CF research team. Patients and caregivers may wish to distribute this Training Manual to their CF care team members or research team to inform them about PCOR and this community resource.

Ultimately, we hope this Training Manual contributes to a comprehensive PCOR training program that can be used longitudinally by current and new CF research teams across the nation, thereby promoting the effectiveness and impact of that research into the future.

A.3 Defining PCOR

Patient-Centered Outcomes Research (PCOR), otherwise termed as "patient-engagement" or "patient and public involvement," entails meaningfully engaging patients, caregivers, and other stakeholders (such as clinicians, payers, and policy makers) throughout the research process. PCOR is increasingly gaining traction among clinical research teams within other specialties in the United States. Partners are valuable to include on research teams because they provide expertise in living daily with the disease or condition being studied. **Ideally, research teams using PCOR methodology invite partners to bring ideas and questions based on their lived experience, with researchers then sharing a variety of possible approaches to study these questions**. Through this exchange, partners begin to understand the research process more fully and can move towards authentically participating in all phases of research.

PCOR is different from traditional research in which researchers come up with the research questions, design the study, and collect data from research participants/patients. PCOR shifts this dynamic and creates a space where patient/caregiver-partners are equal members of the team, helping to guide the study from an idea to results. For example, a PCOR research study may have Focus Groups, with the patient/caregiver-partners helping design, run, and analyze the results from the Focus Groups.

How PCOR Augments Traditional research

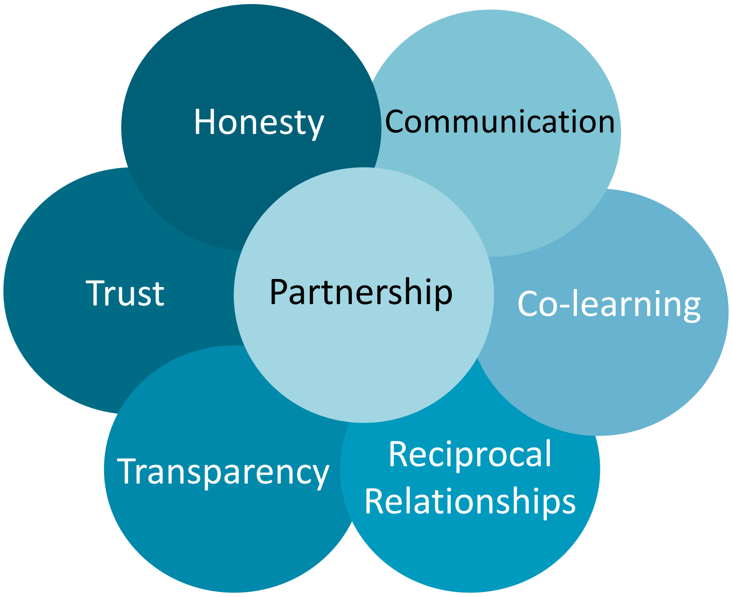
	Traditional Research	Patient-Centered Outcomes Research
Research Objective	Based on epidemiologic data and funding priorities	Patient input in selecting relevant issues
Study Design	Based on scientific rigor and feasibility	Includes scientific rigor, but with patient partner input to ensure study design is culturally acceptable
Grant Writing	Conducted by PI and research team without any patient involvement	Researchers collaborate with Patient-Partners during the entire grant process (Question--> LOI--> Application--> Implementation--> Dissemination)
Recruitment & Retention	Based on scientific issues and methods regarding how to reach patients	Researchers collaborate with patient-partners on recruitment and retention strategies

Adapted from the Colorado Foundation for Public Health and the Environment, Patient & Community Engaged Research Webinar. June 25, 2015.

Table 1. How PCOR Augments Traditional Research

A.3.1. PCOR Defining Principles

The Patient-Centered Outcomes Research Institute (PCORI) has established six core principles for establishing authentic partnerships with patient/caregiver-partners. The principles include communication, co-learning, reciprocal relationships, transparency, trust, honesty, and partnership.



Reciprocal relationships. All roles on the research team are defined collaboratively, clearly stated and shared among team partners. Decision-making is shared.

Co-learning. Patient/caregiver-partners are supported in learning and understanding the research process. Researchers take time to learn about PCOR and the experience of living with CF. Researchers actively engage patients and other stakeholders in the research process. Talent, experience, and contributions of all partners are welcomed and honored.

Partnership. The contributions of patient/caregiver-partners are valued and compensated fairly. Reasonable expectations of time commitments of all members are honored. The unique needs of people with CF are respected and accommodated.

Trust. Transparency. Honesty. Major decisions are made within the group. Information is shared readily with all partners. Team members are committed to open and honest communication.

A.3.2 The Benefits of PCOR

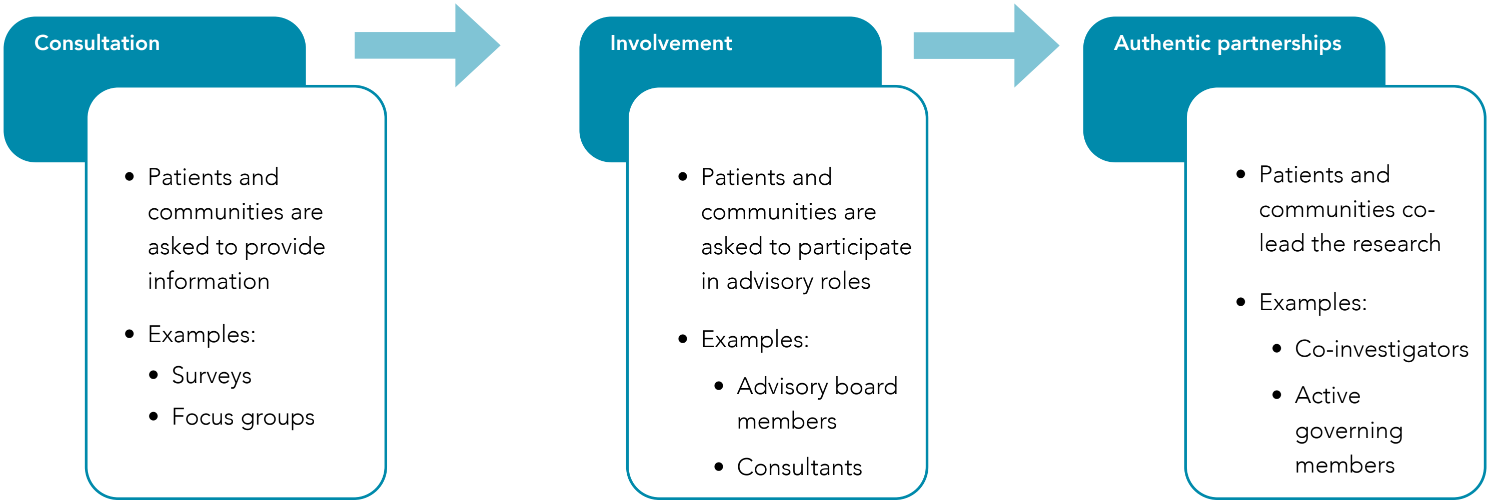
In general, a PCOR approach makes research more applicable to people with CF by including them as members of the research team, rather than just as research subjects. PCOR has been shown to help researchers more successfully recruit research participants and meet enrollment targets in studies. PCOR also builds collaborating skills for both researchers and community members. PCOR has been shown to improve research quality, increase patient trust in both the research and researchers, and positively affect health outcomes.

A.3.3 How Engagement Is Defined

Patients and caregivers can engage with PCOR research teams at different levels. Engagement can range from being as informal as informing or consulting, to including positions that are more formidable, such as having established partnerships (see image below). It will be important for research teams to clearly articulate the level of engagement they are wanting their partners to play and to communicate these expectations in recruitment materials (see "Inviting Patient Partners" in our Launch Guide).

Most funding agencies will want to see details regarding how teams plan to engage patients and stakeholders meaningfully throughout the proposed project. Such details can include responses to the following questions:

- How do you plan to identify and engage patients and stakeholders on your research team?
- Do you show that the roles of patients and key stakeholders are part of formulating the project's questions and design, and that they are participating in the project conduct and dissemination of the results?
- Are roles proposed for patients and stakeholders in any dissemination or implementation plans?



Consultation

- Patients and communities are asked to provide information
- Examples:
  - Surveys
  - Focus groups

Involvement

- Patients and communities are asked to participate in advisory roles
- Examples:
  - Advisory board members
  - Consultants

Authentic partnerships

- Patients and communities co-lead the research
- Examples:
  - Co-investigators
  - Active governing members

A.3.3.1 ENGAGEMENT IN THE CF COMMUNITY

Since the Cystic Fibrosis Foundation (CFF) started engaging patients and caregivers in research nationally in 2014, patients and caregivers have given input on research priorities, care guidelines, CFF programs and policy. While CFF does not actively facilitate PCOR, researchers may recruit partners through Community Voice and Research Voice listservs so that patients can help inform their projects. In 2021, CFF also created its first patient-centered study, called Hero-2, to assess the impact of Trikafta modulator therapy on the daily medications and treatments of people with CF.

The depiction below represents different levels of engagement through activities within the CFF's Community Partnerships department.

Shaping CFF's Program-Level Initiatives

- Broad feedback from community members helps shape CFF's overarching research priorities

Giving input on specific research projects

- Through surveys and focus groups, community members can provide their input on key study-related questions, and researchers can direct their projects towards the topics that matter most to the community

Sitting on a review committee

- Community members can review grants and protocols to ensure they are feasible and aligned with the community's needs

Working on guidelines and quality improvement

- Community members can partner with researchers and clinicians to co-create clinical care guidelines and apply the latest evidence to improvements in CF clinical care

Partnering in Patient-Centered Outcomes Research

- Community members and researchers can collaborate as equal partners throughout the entirety of a research project

People with CF can help shape research in many different ways.

Community members can become engaged with this work through Community Voice and other venues.

A.3.4 Avoiding Tokenism

Tokenism is defined as the practice of making only perfunctory or symbolic efforts to engage patients, caregivers or community members. Research teams can avoid tokenism by incorporating the following practices:

1. **Engagement Structure:** Ensure there is more than one patient/caregiver-partner on the team
2. **Intent:** Engage patient/caregiver-partners throughout the duration of the research project
3. **Relationships**: Create a team environment that builds trust between researchers and stakeholder partners

B. METHODS

B.1 Development of PCOR Training Manual for CF

This CF PCOR Training Manual builds on an educational needs assessment of CF community members conducted in early 2019. The Training Manual Development Group created a pilot training program based on the findings from the educational needs assessment. Four separate training sessions were provided to almost 60 members of the CF community between April and October, 2019. Attendees who evaluated the program requested a guide, that provides specific steps to successfully implement patients and/or caregivers onto research teams. This Training Manual came out of that request and has been developed with input from diverse members from the CF and PCOR community (i.e Training Manual Community Advisory Board). Members on this board include researchers, patients, and caregivers with some knowledge about the importance of patient engagement in research teams. Due to funding constraints, we preemptively limited the Development Board to no more than 15 members total. We aimed to enroll about 6 patients/caregivers, 6 researchers/providers, and 3 institutional stakeholders from CFRI/CFF.

B.2 Recruitment of CF PCOR Community Development Board

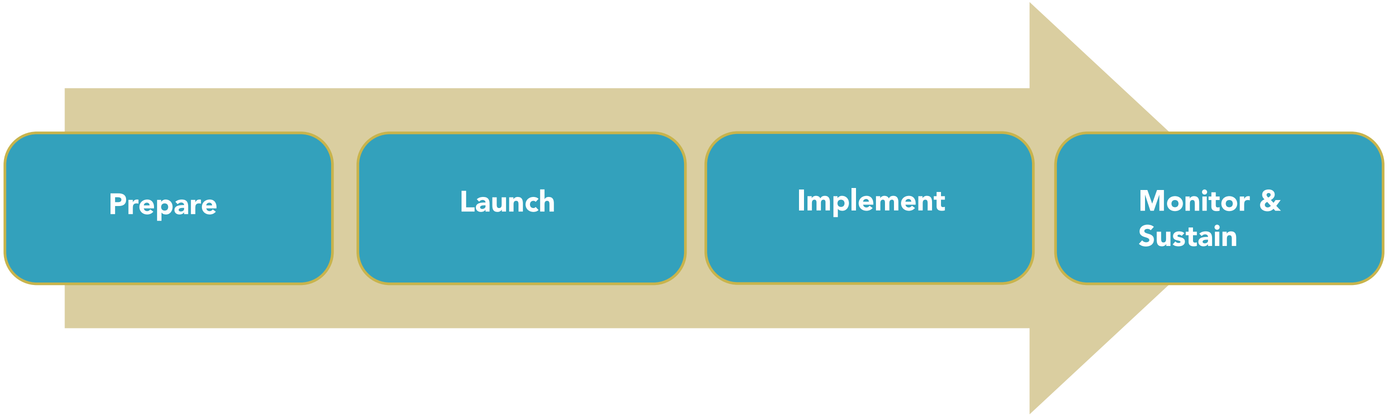
To recruit members, we developed and disseminated flyers to be sent out on listservs from CFF (Community Voice; provider listservs), CFRI (weekly newsletter), Attain Health Foundation, National Organization of African Americans with Cystic Fibrosis (NOAACF), CFReSHC, and through universities such as the University of Washington and the University of Pittsburgh.

To ensure diversity, especially with patient and caregiver stakeholders, we used a questionnaire to collect demographic information such as connection to CF, education level, age, time zone (for geographic distribution), race/ethnicity, gender identity, and type of community (ex. urban, rural, suburban, small town). We also asked about prior experience working on research teams (not as a research subject) and interest in PCOR or patient-engaged research. Finally, to screen for applicants who were committed to our project goals, we asked them to review and provide feedback on our Best Practices Guide for Virtual Engagement (https://familymedicine.uw.edu/pcor-guide/)

We received 12 patient/caregiver partner applications, and chose participants based on demographic criteria, experiences with research, and their feedback for the user guide.

B.3 Conceptual Framework

The development of this Training Manual is guided by the Quality Implementation Framework (QIF). The QIF identifies four phases of implementation, which we have adapted to the following steps: (1) Prepare, (2) Launch, (3) Implement, and (4) Monitor & Sustain.



Step 1: Prepare: This is the first step for the PCOR champion to obtain buy-in and investigate institutional rules and regulations regarding partners participating on research teams.

Step 2: Launch: In the second step, the PCOR champion uses the Launch Guide to invite partners onto the research team and create a space for effective partnerships. It also provides suggestions about what components to include in team agreements.

Step 3: Implement: In step three, the PCOR champion uses the Implement Guide to steer the newly formed PCOR team on putting together grant applications and integrating partners into each stage of the research project.

Step 4: Monitor & Sustain: In the last step, the Monitor and Sustain Guide provides suggestions for supporting success, handling disagreements, adding new partners to the team, and implementing continuous improvement of the PCOR team.

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Step 1:
Prepare

This section is tailored primarily to CF PCOR champions to learn skills and gather institutional policies that will help set the stage for the successful incorporation of patients and caregiver partners onto their research teams.

For the purposes of this document, when the term "partners" is used, it is inclusive of patient and caregiver-partners.

Prepare includes:

1. Identifying a PCOR champion
2. Completing PCOR training for researchers
3. Gaining leadership and institutional buy-in
4. Inviting patient/caregiver-partners onto the research team

This table of contents is a starting list of steps for this stage, which you can adapt for your needs.

Prepare Activities

WHAT IS MEANT BY PCOR, CO-PRODUCTION AND PATIENT ENGAGEMENT

Patient-centered outcomes research (PCOR) Is a type of research that includes patients and caregivers as valued partners on research teams and encourages them to participate fully in all aspects of the study.

Co-production focuses on creating a space and a product together with partners. The result is something that has received equal input from both researchers and partners.

Patient engagement is how patients and caregivers are included on research teams. Individuals who advocate for and support implementation of a new program, policy, or process.

Champion is an Individual who advocates for and supports implementation of a new program, policy, or process. Effective champions are generally respected members of the institution and/or research team, have some authority to direct resources to support implementation, and possess a personal commitment and passion for seeing the innovation through to completion.

A PCOR CHAMPION:

- Gets trained on patient-centered outcomes research (PCOR), community-partnered research and the science of engagement research
- Builds skills in group facilitation
- Finds funding or time during the regular work week to support foundational work needed to build a well-functioning engagement team
- Works with institutional leadership to familiarize themself and team with institutional policies about community partners working on research teams

HELPFUL HINT

It is important to know what your goal is in bringing patients and caregivers to the table; this will help inform how you engage with them.

PCOR TRAINING FOR RESEARCHERS

PCOR, or patient and public involvement, entails meaningfully engaging patients, caregivers, and other stakeholders (such as clinicians, payers and policy makers) throughout the research process. It is increasingly gaining traction among research teams in the United States. Patient engagement on research teams has been shown to improve research quality, increase patient trust in both the research and researchers, and positively affect health outcomes

One opportunity for researchers to learn about PCOR is through the Patient-Centered Outcomes Research Institute (PCORI) at https://www.pcori.org/engagement/research-fundamentals. Additional resources are listed in Table 1 below.

Table 1. Additional resources for researchers and partners to learn about PCOR

Title	Content
Resources for researchers	
Community-Engaged Research: A Quick Start Guide for Researchers https://accelerate.ucsf.edu/files/CE/guide_for_researchers.pdf	Prepares researchers for future work with community-based organizations, other clinicians, or community stakeholders
Stakeholder engagement strategy selection tool https://dicemethods.org/	Web-based tool with (1) an Education hub and resources to learn about stakeholder engagement and (2) an Interactive selection tool to explore engagement strategies
Principles of Community Engagement (2nd Edition) https://www.atsdr.cdc.gov/communityengagement/	NIH Clinical and Translational Science Award publication providing practical information about engaging community partners in research
Researching Health Together: Engaging Patients and Stakeholders, from topic identification to policy change https://us.sagepub.com/en-us/nam/researching-health-together/book265162	Textbook on community engagement in health research
Resources for partners	
Preparing for Research Partnerships: Providing Training for Partnerships https://ipfcc.org/bestpractices/sustainable-partnerships/preparing/providing-training.html	A training toolkit for partners preparing for research
Resources for partners and researchers	
Strategy for Patient-Oriented Research: SPOR https://cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf	A framework for engaging patient-partners in research
PCORI Fundamentals Training Modules https://www.pcori.org/engagement/research-fundamentals	A basic training course for partners and researchers who are new to PCOR and research
Family/Youth/Researcher Education (FYREworks) https://www.fyreworkstraining.com/	A training for both partners and researchers on how best to work together
CF Community PCOR 101 for Researchers/Providers and Patients/Caregivers https://familymedicine.uw.edu/pcor-guide/wp-content/uploads/sites/13/2021/12/PCOR-101-for-CF-Researchers-and-Partners.pdf	An introductory power-point presentation presented to CF community stakeholders

Training in Facilitation Skills

Training in facilitation skills can help researchers ensure all members of the research team have a “voice at the table” and contribute to important decisions in their area(s) of expertise. PCOR champions and other research leads should aim to build their skills in facilitation to ensure equal involvement of partners on the research team. Well-facilitated team meetings are important to help partners feel welcome and comfortable so they readily share ideas and concerns as experts living with CF. Please see the “Facilitation Skills” supplement on page 24 at the bottom of this guide for an example.

Table 2: Additional resources for researchers to build skills in facilitation

Title	Content
6 Essential Skills of an Effective Facilitator https://www.linkedin.com/pulse/20140619061555-1334077-6-essential-skills-of-a-effective-facilitator	A LinkedIn article that briefly outlines the skills a facilitator needs to be successful
Community Tool Box: Conducting Effective Meetings https://ctb.ku.edu/en/table-of-contents/leadership/group-facilitation/main	Outlines four phases of an effective meeting, as written by Community Toolbox
Development team's list of effective facilitation techniques found in the Prepare Supplement at the end of this guide on page 8	A list of facilitation skills created by the same team who developed this guide

Table 2 has a few resources for PCOR champions to build their facilitation skills.

LEADERSHIP AND INSTITUTIONAL BUY-IN

Educating institutional leaders about what engagement research entails and knowing your organization's policies ahead of time streamlines workflow when research teams have partners. The following steps prepare research teams to implement PCOR and obtain leadership buy-in at their institution:

Find Resources to Support Foundational Work

PCOR requires more time and effort than what is normally required to build a research team. Thus, PCOR champions and CF research teams should be prepared to divert resources within the institution to get training in PCOR methodology and understand institutional policies prior to partner onboarding and grant funding.

Assess for Organizational Readiness

The implementation science literature suggests that readiness is an essential part of successfully implementing an innovation. Engaging partners as co-producers on the CF research team is the innovation in this context. Ask your team the questions from the "Assess for Readiness" supplement on page 26.

Communicate the Need for and Benefits of PCOR

As part of assessing for readiness, research teams should be prepared to talk about the need for and the benefits of PCOR within their organization. See more in the "Benefits of PCOR" supplement on page 27.

How will you share with other researchers and your own institution the necessity of PCOR and the benefits of this type of research?

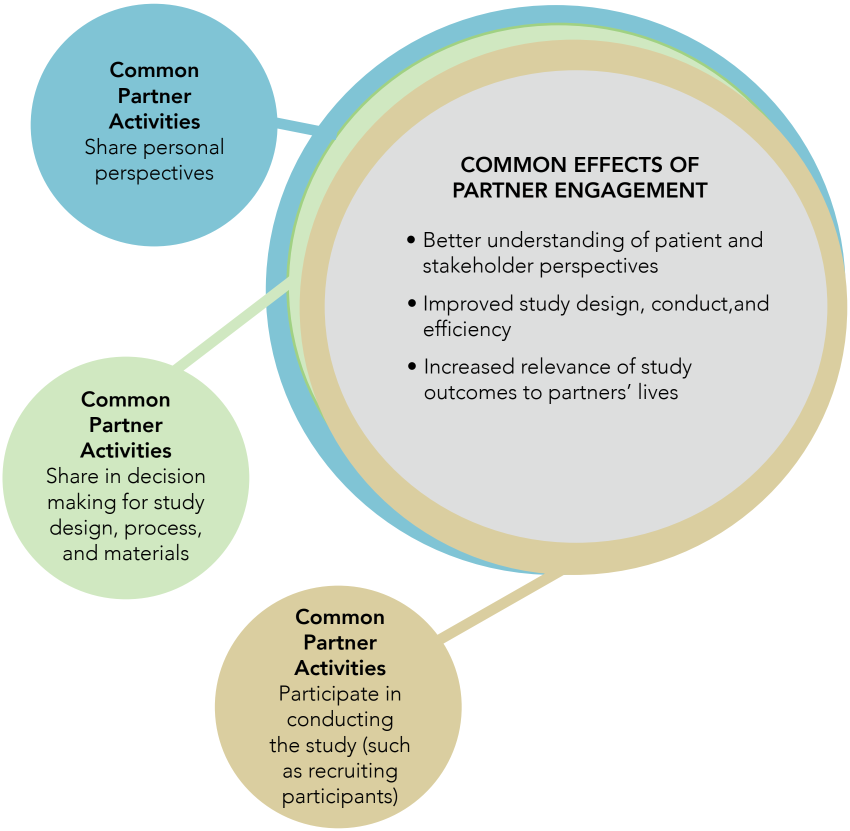
Researchers bring their subject matter expertise to the project, as well as their knowledge about research and research practices. Partners provide insights into what it is really like to live with CF. Ideally, research teams using PCOR methodology invite patients/caregivers as partners to bring ideas and questions based on their lived experience with the disease, with researchers responding by sharing a variety of possible approaches to study them. With this exchange, partners begin to understand the research process more fully and can move towards co-producing throughout each phase of the project.

Partners often have other skills that may enhance the research process. For example, partners can serve in a variety of roles including as advisors, leaders of focus groups, presentations, and co-authors on publications.

A research team that was conducting a survey study about sexual and reproductive health services within CF Centers quickly discovered that each of three patient partners on their research team had expertise, in addition to their lived experience with the disease, that they could share. One patient was a former sex-education instructor and was able to help the research team with clarifying questions asked on the survey. Another patient was tech savvy and helped the research team get up and running with the use of online platforms for meetings, document sharing and every day communications. The third patient partner enjoyed painting and drawing. This patient was happy to help design team logos and beautify flyers and announcements going out to community partners and other research teams.

Figure 1. A diagram of the benefits of patient engagement

This figure presents themes identified through qualitative analysis of open-ended responses collected via the PCORI annual awardee reports and voluntary surveys of research partners; N=261 reports from awardees and partners.



When researchers, patients, and other stakeholders come together as partners, the result is synergistic, making the research far more impactful to partners' lives. Research done with partners is research that will be used. To read about ways partners contribute to research teams, see the supplement on page 26.

Other ways to communicate the benefits of PCOR to academic leaders is through testimonials. Using patient and researcher testimonials provides relatable faces and context to PCOR and explains why and how PCOR is valuable. See the link to the PCORI website for PCOR testimonials in the Engaging in Stakeholder Driven Research module. https://www.pcori.org/engagement/research-fundamentals/engaging-stakeholder-driven-research

Look into Human Subjects Protection Office (IRB) stakeholder policies

HELPFUL HINT

Questions the IRB might ask:

- **Is the project research?**
- **Is the patient/caregiver a human subject?**
- **How can they be sure that the protection of research subjects is upheld?**

Inquire about your institution's Human Subject Protection Office (or Institutional Review Board) policies regarding patients or caregivers who participate in research as partners, not as research subjects. Explain your partners' qualifications as well as their roles and responsibilities. It may also be helpful to provide your IRB with information about the value of PCOR and why it is important to have partners participating on research teams.

Some institutions may require that partners provide consent to participate on university-based research teams. This requirement is not ideal because it sends a subtle message to partners that they are not equal members of the research team, undermining the purpose of PCOR. Institutional requirements for partners and other community members to sign consents often stem from preconceived notions, or the IRB's lack of understanding of the role the partner will play as a member of the research team.

PCOR Champions should determine whether Protection of Human Subjects (IRB) training will be required.

HELPFUL HINT

Protection of Human Subject training for patient/caregiver partners is NOT REQUIRED if: Patients or other stakeholders act strictly as advisors.

Protection of Human Subject training for patient/caregiver partners IS REQUIRED if: Patients or other stakeholders plan to interact with study participants or data.

Some institutions accept or offer Human Subject Protection training specifically for community members, while others require community members to do the same training as researchers. Please check with your Human Subject Protection Office about what IRB training they accept.

Two potential IRB certification programs for partners are the University of Pittsburgh Community Partners Research Ethics Training at https://ctsi.pitt.edu/education-training/community-partners-research-ethics-training/ and University of Illinois at Chicago CIRTification Program at https://ccts.uic.edu/tools/cirtification/online/.

Be sure to communicate with your potential partners or other stakeholders whether IRB training will be required and how many hours the training will take. Some partners will not mind having to do the training, while others may find this as a barrier to participating in PCOR activities.

Gather Institutional Policies on How to Compensate Outside Community Members

PCORI recommends compensation for all persons contributing to the research team, including partners. Compensation is a way to show you value the contribution partners bring to the study. Discuss with procurement administrators about institutional policies regarding the payment of community/partner members.

Keep in mind that people with CF may be on government assistance, supplemental security income (SSI) or on social security disability income (SSDI) and unable to earn more than a certain amount per month or risk losing their assistance. Thus, PCOR champions should be ready to provide flexible payment schedules.

HELPFUL HINT

Consider compensating partners monthly instead of paying as a single sum at the end of the project. Alternatively, if approved by the Sponsor and the academic institution, offer in-kind compensation by supporting partners with conference or travel fees, headphones, or cameras for remote meetings, or other services partners might need to participate on the PCOR research team.

Partners may need financial or other support to participate in PCOR meetings. Providing support can help diversify the types of partners participating in PCOR. For example, partners who are parents may benefit from childcare support when they attend PCOR meetings.

Institutional Information Technology (IT) Security

Some institutions ask partners to register as volunteers to obtain access to secure information. Institutions may also require partners to use an institutional email account to keep emails that contain research team correspondence or study information secure. PCOR champions should be aware of IT policies for outside stakeholders.

Congratulations, you are now prepared to start your PCOR journey. To continue, please go to the Launch PDF.

Example Facilitation Skills

Use the bullet points below for some first steps to take when facilitating meetings and team events:

- **Set Expectations.** Create an agenda for meetings and send it out to all participants ahead of time to give people time to gather their thoughts. Start each meeting by reviewing the agenda to create an overview of the meeting.

- **Create a welcoming environment.** Use open and welcoming body language and tone of voice. Smile and welcome individuals to the meeting. Use first names, without titles, to create a level playing field. Create meeting ground rules together as a team (see Generating a Governance Document in our Launch Guide) that can be referred to if meetings get tense.

- **Encourage participation from all members**. At the outset of the discussion, announce how you will call on people to set the expectation that everyone will participate so that it does not feel like you are picking on any one individual. Using an ordered way of calling on people allows people who are less likely to speak up the opportunity to do so and prevents individuals from dominating the discussion.

Call on people using a Z-A name scheme, starting with the person whose first name is the last alphabetically.

- **Create opportunities for partners to share nonverbally**. Not everyone engages in the same way. Provide options for nonverbal engagement such as asking for feedback on written surveys, study questions, and publications through shared documents. This also allows team members unable to attend a meeting the ability to contribute ideas. **Learn more about platforms you can use to share documents in the appendix.**

Start the conversation with a question on a shared document (ex. "What is your idea for X"), set a timer for 10 minutes and allow people to write their ideas and +1 other peoples' ideas. Then open it up for discussion.

- **Reflection on and rephrasing of** discussion points can help some learners retain the information, clarify or summarize a point, and serve to move the discussion forward. *You can start with "what I am hearing from you is…"*

- **Ask questions that get people talking**. They can be open-ended, follow-up, or more specific questions. Stay away from yes/no questions as they will not result in rich discussions. Resources to help research teams with training and communication are available in Appendix 1.

- **Keep discussion on task.** If the discussion is getting bogged down in the details, or is on a tangent, firmly but gently steer the discussion back to the item at hand for example, say "this is such a rich discussion on X point, but I want to bring us back to X topic." You can also use meeting ground rules to empower the whole team to step in and steer the conversation back on track.

- **Maintain Engagement.** Watch participants' body language and facial expressions. Are eyes glazing over, or are they obviously doing other things on their computer, not paying attention? Are they confused? Bring them back to the meeting with a direct question, or slow down and ask if anyone needs clarification.

- **Create a continuous feedback loop** to assess how your team, and especially your patient and caregiver partners feel about the meetings. Create anonymous surveys for team members to fill out to find out how they thought the meeting went, if they felt included, and whether the research team was clear in their communication.

End the meeting with a poll asking participants to rank it on a scale of 1 to 5 where 1 indicates that the meeting went poorly and 5 indicates it was excellent. Alternatively ask your team what one word they would use to describe the meeting.

Ways to encourage participation from all team members:

- **Ask** for input from those not speaking up
- **Practice** empathy
- **Listen** attentively
- **Reflect** back what you heard
- **Don't** offer advice, suggestions, or interrupt with own experience
- **Ask** open-ended questions

Assess for Readiness

To determine if your team is ready to begin a PCOR project, first ask yourselves the following questions:

1. On a scale of 1 to 10, how big of a priority is engagement for our research team? Why? What are the concerns or competing demands?
2. What does the research team hope to gain by having CF patients/caregivers on their research team?
3. Is the CF Center leadership, department or institution supportive of making changes to research teams?
4. What are our priorities for types of patients and other stakeholders on our team? What are the skills and experiences of the people we are hoping to learn from and collaborate with?
5. Who will be the PCOR champions for the team?

The Benefits of PCOR

Although medical teams have had to quickly shift in many ways during the COVID-19 pandemic, evidence-based research is often slowly adopted by clinicians as part of routine care. In general, a PCOR approach makes research more applicable to people with CF by including them as contributing members of the research team, rather than just as research subjects. PCOR has been shown to help researchers more successfully recruit research participants and meet enrollment targets in studies. PCOR also builds collaborating skills for both researchers and community members. PCOR has shown to improve research quality, increase patient trust in both the research and researchers, and positively affect health outcomes.

By regarding patients/caregivers as content-experts, researchers are better able to gain knowledge about what CF looks like in different contexts. Patient/caregiver experiences help lay the groundwork for understanding CF comprehensively. Patient/caregiver-partners on research teams can reduce disparities and address social determinants of health, and lead to more effective interventions. Better interventions and better understanding of social contexts can, in turn, lead to improved CF studies.

While the Patient-Centered Outcomes Research Institute (PCORI) is a prominent funder of research focused on patient- and stakeholder-engagement, research funding agencies are increasingly encouraging the inclusion of patient stakeholders on grant applications by making such engagement a requirement for funding. Patient engagement is increasingly emphasized in grants funded by the NIH, CDC, private foundations, and industry/pharmaceutical companies. As more patient/caregiver-partners will begin to join CF clinical research teams, CF researchers will need adequate skills to successfully integrate these new members. Engaging patient/caregiver-partner on research teams for the long-term requires a sustained approach to support team collaboration and to ensure principles for engagement are actualized.

How Partners on Research Teams Benefit the Study

Patient/Caregiver-partners can help with:

1. Understanding the daily challenges of living with CF and patient perspectives over time.
2. Creating a lasting and mutually beneficial partnership with patients in this community.
3. New ideas about the research questions that are already being asked. New research questions that researchers have not considered (ex. menstrual study to look at the effect of menstrual cycles on CF symptoms)
4. Make your research relevant. Is this what the CF community needs? Wants? What language should you use to connect with CF patients?
5. Recruitment. Where can you recruit study participants? Are there listservs or secret facebook groups that only people with CF can access? Is this research people with CF would want to participate in? Do the flyers contain information that will attract people to the study and make them want to participate?

Step 2:
Launch

This section is tailored primarily to CF researchers and the steps they should take after preparing their teams and institutions for PCOR. These are essential first steps in creating a successful PCOR team. For the purposes of this document, when the term "partners" is used, it is inclusive of patient and caregiver partners.

This table of contents is a starting list for this stage, which you can adapt for your needs.

Launch Activities

DEVELOPING RESEARCH PARTNERSHIPS

Engage Partners Early

Start engaging partners as future team members and gathering ideas for research questions and studies early, before the grant opportunity is identified. Early engagement also allows the team to discuss team agreements and communication, which are detailed below.

HELPFUL HINT

- **Engage partners early, preferably before or while developing a research proposal.**
- **Use a variety of sources to find and reach out to potential partners.**

For an overview of Best Practices in Engaging Stakeholders, see PCORI's "Preparing Team Members for Partnership." https://research-teams.pcori.org/stakeholders#Practicing%20Effective%20Team%20Communication

INVITING PARTNERS ONTO THE RESEARCH TEAM

Decide on the Number of Partners to Have

Research teams should consider the number of partners to include on their team. Including several partners on a single research team can help diversify the patient voice and avoid tokenism.

Time off needed by partners is another consideration regarding how many partners to include on a research team. People with CF may have other circumstances that affect the amount of time they can dedicate to your team. Teams will want to have good partner representation should one stakeholder become unavailable.

A partner on a PCOR team was hospitalized and missed a month of developing a product for the team. Luckily, the team had a community advisory board that could represent the patient voice in the project, and the grant was not delayed.

The number of partners also depends on team resources. In general, we recommend starting small, with 2-3 partners. Teams can grow as agreements and processes are established, specific needs to conduct the research are identified, and funding is secured.

Create a Flyer to Recruit Partners

Create a flyer that outlines the partner's role on the CF Center research team. The flyer should include information about partner expectations, compensation, and time commitment. It should also include frequency of meetings and the amount of work that will be needed between meetings. It should be written in clear, easy to understand language and all acronyms should be defined.

Choose Partners

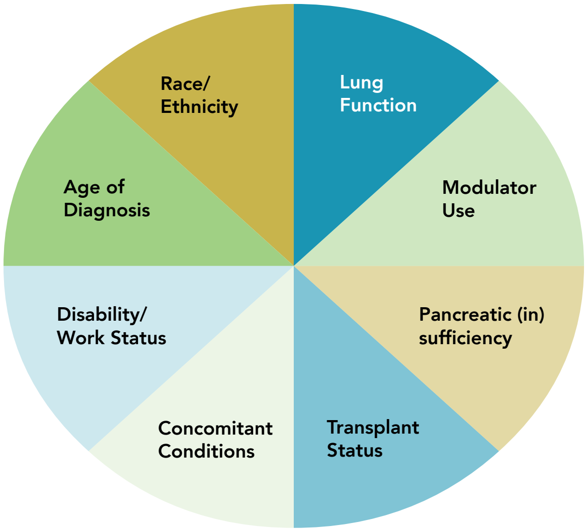
Diversifying your team can lead to new ideas and open others' eyes to different experiences that relate to the study.

Possible activities for selecting diverse partners include:

- Run an informal focus group with multiple partner applicants to see how partners interact and what skills they add to the team (i.e. some people are better at facilitation, tech, identifying research questions, etc.).
- Work with CF care centers to identify partners. Speak to potential partners to ensure the work is a good fit with their interests and abilities.*
- Generate a questionnaire that asks about basic demographic information (see fig 1). Additionally, the questionnaire can ask partners to report their skills and strengths.

*Ideas for places to recruit partners are located in the "Where to Find Partners" supplement on page 37.

Figure 1. Types of Diversity in CF



Approaching Partners in Your Own CF Center

As a physician/researcher, it may not be appropriate to ask your own patients to join your PCOR team. Some patients may feel pressured to join, and this may affect how they participate and whether they feel comfortable being honest with the group.

If you do decide to ask patients within your own CF Center, consider:

- How do you make the question as pressure free as possible? How can you show your patients that saying "no" will not affect their relationship with you or their quality of care?
- What is the best timing? It may not be appropriate to ask during a formal clinical visit.
- Think about who is best suited to address your patients. Consider medical assistants, receptionists, research coordinators, or existing team partners as potential team members to invite new partners onto your team.
- Introducing the invitation as part of an overview of the visit and following up in a few days. The end of a visit may not be the most appropriate time to invite partners because patients are often tired and mentally drained after a long day at the CF clinic. They are eager to get home to pick up children, eat, rest, or attend to other responsibilities.
- A patient who has known you longer and/or knows you better may be more comfortable being honest with their feelings about being invited to join a PCOR team.
- When you approach them, explain PCOR thoroughly. Let your partner know exactly what it is and what you are asking of them, and why you think they would be a good fit.

> *A research coordinator wanted to recruit a patient for a study. The CF physician/researcher suggested that the research coordinator come in and explain the study to the patient while the physician was performing a nasal exam. The research coordinator opted to come back later in the visit when the physician was not there, so the patient would not feel coerced.*

CREATING A SPACE FOR EFFECTIVE PARTNERSHIP

Onboarding Partners

Onboarding partners helps to ensure that everyone, including the partners, share common language and understanding. This sets the stage for teams to co-create successfully. Onboarding for partners includes basic research training. See Table 1 in the Prepare Guide for basic research training and PCOR training resources.

The Cystic Fibrosis Learning Network (CFLN) offers helpful resources for patient/caregiver onboarding. Information about the CFLN is included in the list of Active Learning Programs facilitated by Cincinnati Children's Hospital. For more information, contact Kathy Sabadosa (ksabadosa@cff.org) at the Cystic Fibrosis Foundation. https://www.cincinnatichildrens.org/research/divisions/j/anderson-center/learning-networks/active-emerging

Create a Welcoming Environment

https:www.pcori.org/sites/default/files/TeamScience-SWOG-Field-Guide.pdf

Figure 2. Leveling a power differential on a PCOR team

To ensure honest and open input from partners, they need to feel welcome on the research team. Knowing their voices will be heard and respected encourages participation. Developing skills to create welcoming environments helps researchers obtain participation from all team members (See "Facilitation Skills" in the Prepare Guide supplement page 24).

Clarify How Equal Partnerships Will Be Established

In PCOR, patients and caregivers are active partners in research, but they may often be intimidated to speak in front of researchers. Thus, teams should incorporate processes to level the playing field so that partners feel comfortable to actively participate and offer feedback on researchers' ideas.

> *When we first started our PCOR team, partners were reluctant to speak freely in front of researchers and clinicians due to the fear that something said would get back to their CF Care Team. As a solution, only the designated PCOR champion met with partners for the first several years. The PCOR champion acted as a liaison between the researcher group and the partners until the partners felt comfortable speaking with all the researchers.*

HELPFUL HINT

Below are some questions your team may want to review to create a welcoming environment:

- **What concerns do you have about patients/caregivers as equal members of the research team?**
- **What are ways research team members can level the power dynamic?**

Some ways to create a sense of equality with partners:

- Use first names (avoid formal titles like Dr. or Professor)
- Recognize and appreciate different talents and experiences verbally or in writing
- Encourage partners to lead activities:
  - ◊ Assign partners regular team roles, such as meeting facilitator, note-taker, and timekeeper
  - ◊ Co-present with partners at conferences
  - ◊ Empower partners to write about the project/research for non-peer-reviewed publications for CF patients

Build Relationships

Building stronger relationships can help develop partners' comfort on the team. When partners are comfortable, they may give more information about their experiences. Building relationships creates team cohesion and helps avoid miscommunication. Strong relationships allow the PCOR team to work together better.

Start building relationships on your team as soon as possible. The entire team should participate in relationship building.

HELPFUL HINT

Use this checklist below as a starting point for team agreements.

- **Communicate need/benefits of PCOR** – PCOR increases quality of research, trust between patients/caregivers & providers, empowers everyone in the community, and leads to greater health equity
- **Outline practices that counterbalance resistance to change** – How do we recognize that being able to speak about the lived experience of having CF is an important aspect of research?
- **Create policies that enhance accountability** – Make sure there are several CF partners on each research team to avoid tokenism. Ensure members of the research team are trained in facilitation to make sure everyone feels welcome. Include IRB policies and how to reimburse partners who are not research subjects.

Relationship building can be achieved through a variety of methods. For some examples of activities you can do with your team, see the "Building Relationships" supplement on page 38.

Teams are motivated by passionate leaders. Share your passion about CF (care, research, patients, communities). Passionate leaders make the work more enjoyable. They help motivate their teammates to work harder and feel appreciated. The result is that every team member feels a stronger sense of satisfaction. Encouraging strong relationships and maintaining positive leadership will also promote a sense of fun and enjoyment.

It can be harder to build relationships virtually because body language is harder to read and small talk is more difficult. Consult the Guideline for Online PCOR Engagement for tips to enhance relationships online at https://familymedicine.uw.edu/pcor-guide/

HELPFUL HINT

Think about the best teams you were a part of.

- **How did you build relationships?**
- **What was most effective?**
- **When was your team most productive?**

ESTABLISHING TEAM AGREEMENTS

Team guidelines can be established through team agreements, a team charter, or a governance document. The team charter or governance document is co-created with researchers and partners and can be updated as needed.

Documenting team agreements is important before your PCOR team begins their work. A list of items to include in your governance document is in the "Generating a Governance Document" supplement on page 40.

HELPFUL HINT

For grant applications, an effective team charter, team agreements or governance document can translate into an engagement plan. Having established agreements in place shows potential funders that the engagement team is already established and is a high-functioning partnership.

Are you unsure of what your governance document should look like? Below is a table with links to governance documents from previous PCORI awardees.

Table 1. Example Governance Documents from Previous PCORI Awardees

Title	**Contents**
Governance document for Patient Outcomes Research to Advance Learning (PORTAL) Network (see appendices B, C, D) https://www.pcori.org/sites/default/files/521-PORTAL-Governance.pdf	Governance Document outlining roles, responsibilities, and decision-making
Inborn Errors of Metabolism Collaborative (IBEMC) QUEST Project Governance Document https://www.pcori.org/sites/default/files/QUEST-Governance-Document.pdf	Governance document outlining roles and expectations within the team
Patient-Centered Network of Learning Health Systems (ADPCPRN) Governance Policy https://www.pcori.org/sites/default/files/512-AD-PCPRN-Governance-Policy.pdf	Governance policy outlining roles, expectations, and study processes

Address Concerns About Confidentiality

What do we mean by "confidentiality"?

- Patient information is protected through the Health Insurance Portability and Accountability Act (HIPAA). However, when those patients and caregivers volunteer to be a partner on a research team, they are not covered by HIPPA. During your work together, they may disclose personal or confidential information about themselves as a way of sharing their experience as someone living with the disease. This information may not be shared outside the team unless partners have given explicit permission to do so (ideally in writing).
- Team agreements should articulate partner preferences for disclosure of their name and/or photo outside the team.

A newly formed interdisciplinary research team asked three patient partners how they would feel if their names and photos were included on the institutional departmental Facebook website. One patient partner was happy to list her name and post her photo. The other two did not want their names or photos posted, because their disease was confidential from their workplace and they feared discrimination if their employers found out that they had CF. Thus, the team agreements stated that partners had to agree, in writing, to having their name and photos used on public facing websites prior to posting.

Articulate How Decisions Will Be Made

Team agreements should also include how decisions will be made.

Power and team dynamics have a strong influence on how teams make decisions and whether those decisions are made equitably. Teams should discuss approaches to decision making and agree on a process. Are there some areas where partners make decisions, but other areas where the researchers do? Groups may make decisions by voting, consensus, or a blended process. Practicing your process early and often will support the team when making decisions as a group becomes difficult.

Keep in mind that consensus is different from majority rule. Through consensus, an agreement is made that reflects compromise between all members of the group. Consensus should strive to be "win-win" and provide a decision that everyone involved can agree to. For more information about consensus see Seeds for Change's explanation on consensus decision making at https://www.seedsforchange.org.uk/shortconsensus

Write A Mission Statement

Effective teams have a shared understanding of the project, its structure, and commitments. Successful teams share a mission and purpose for the work they have come together to do.

Create A Communication Plan

A communication plan outlines how your team shares information, along with the software, that will be used for meetings and messaging. Consult the "Guideline for Online PCOR Engagement" for tips on software or programs that can enhance your team's functionality at https://familymedicine.uw.edu/pcor-guide/

Traditionally PCOR teams communicate in-person, but for CF PCOR teams in particular, communicating online allows teams to include more than one partner, avoiding tokenism. Additionally, teams meeting virtually can include members from distant locations.

A written communication plan in the team agreements includes:

- How to best communicate with partners about questions and concerns that arise between meetings. Examples include Email, Slack, WhatsApp, or Microsoft Teams.
- Ways collaborative documents will be shared with all team members. Examples include Google Docs or Microsoft Teams.
- Decisions about where to meet, virtually or in person. It is understood that most CF teams with patient partners will meet virtually. Thus, teams may also need to agree on their conferencing platform for team meetings. Examples include Zoom or BlueJeans.

Establish Meeting Times

Partners often have other responsibilities and may not be able to meet during typical business hours. Since CF is a complex disease, PCOR teams also may encounter absences due to illness. Agreements should stress that partners' health is a priority and outline how the team will navigate alternate ways to engage for partners who take time off for CF exacerbations and other health-related matters.

Ways to engage partners in regular team meetings:

- Switch up the time the team meets, or consider meeting in the evening or on weekends
- Be conscious of time zones
- Agree on earliest and latest times all members of the team are able to meet
- Record team meetings that can be watched later and commented on by partners
- Meet individually with partners, outside of meeting times
- Provide written materials about what occurred in the meeting

Other Agreements Related to Compensation and Institutional Processes

Team agreements should also include:

- Amounts and ways in which partners will be compensated.
    - ◊ The amount a partner is paid should be reflective of their contributions to the team or grant project. For examples, see the "Sample Stakeholder Engagement Plan" supplement on page 13, or PCORI's Compensation Framework at https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf
    - ◊ Consider including compensation for work done between meetings for partners who miss meetings due to illness or scheduling conflicts.
    - ◊ Delineate how partners will invoice or be paid according to institutional policies.
    - ◊ Also see "How to Compensate Outside Community Members" in the Prepare Guide.
- Institutional processes related to IRB training or IT security (see appropriate sections in the Prepare Guide).

You have completed the Launch section.

Where to Find Partners

1. CF Listservs and nonprofit organizations
    a. Cystic Fibrosis Research Institute (CFRI) Weekly newsletter
    b. Cystic Fibrosis Foundation Community Voice
    c. Attain Health
    d. Boomer Esiason Foundation
    e. CF Roundtable blog and quarterly newsletter
2. General Research Listservs (you may need to budget these into your grant)
    a. Rare Patient Voices
    b. Savvy Coop
    c. WEGO Health
3. Social Media
    a. Build relationships with moderators of closed and secret Facebook groups populated by people with CF -- there are tons! You can ask your patients/caregivers for recommendations and an introduction. Some groups will not allow researchers, but your partners may post for the team.
    b. Some advice: Do not post a link to an application or survey on a public Facebook or Instagram page-- it will immediately be filled by spam bots.
4. CF Care Centers
    a. Take the time to call less-engaged patients and families. You should never feel like you are coercing patients into joining your team. If you do, we suggest having a research coordinator or other staff member approach the patient or caregiver instead
    b. Recruiting at care centers can target a diverse population of people who are not plugged into CF organizations
    c. Use caregivers to engage the unengaged (e.g. spouses, parents)

Building Relationships

Below are ideas for how to build relationships on your CF PCOR team

1. **Have social meetings to get to know one another, especially when integrating new team members.**
    a. One way to accomplish this is to regularly schedule unstructured social meetings during normal meeting times in which you agree to talk about anything but the project. This would not be a working meeting, but a meeting to get to know each other.

    b. Another way is through structured social meetings, or "team-building events." There are many ideas online for games to play in virtual meetings, questions to lead discussions, and activities to do together.

2. **Share personal information.**
    a. Researchers: do not be afraid to be vulnerable. It will help level the playing field, create a bond that keeps partners invested in the research, and humanize you as a person who exists outside of the context of the project.

    b. It shows that other team members can be vulnerable as well. This is particularly important for patient/caregiver-partners who may share deeply personal experiences and feelings about CF. Vulnerability shows that your meetings and your project are a safe and open space for everyone.

    c. Social meetings are an opportunity for this vulnerability. You can talk about your family, hobbies, or a struggle you have had.

3. **Start each meeting with ice-breaker questions.**
    a. Ask icebreaker questions at the beginning of your meetings. They are a good way to get to know one another. They help to start meetings with energy and fun and makes it easier to maintain momentum, investment, and interest as the meeting progresses. This is also a great moment to check-in with your team and see how everyone is doing.

    b. Finding icebreakers is as easy as doing a quick google search. Finding icebreakers can be a task shared and rotated throughout the team.

Example icebreakers:

- What is your favorite or most used emoji?
- If you could travel to any place in the world, without restrictions, where would you go?
- If you could have any superpower, what would it be?
- What is your favorite item you have bought this year?
- If you had to delete all but three apps on your smartphone, which ones would you keep?
- As a child, what did you want to be when you grew up and why?

If your team does not have time for an icebreaker at the beginning of meetings, consider other ways to get to know one another. An example of this may be quick bios that you share with one another. These bios should not have experience, titles, or educational background on them. Instead, they should include fun facts. You can use some of the icebreaker questions as ideas for questions to ask on these bios.

4. **Address one another by first name, no titles allowed**.

    a. Titles will make the team hierarchical and one of the main tenets of PCOR is that patient/caregiver-partners are equal members of the team.

    b. Leveling the playing field can mean that team members are more honest about their thoughts on the project and their feedback. This is particularly important in the realm of feedback. It can be difficult to provide honest feedback on a hierarchical team. We encourage continuous feedback to improve the team and team experiences.

5. **Skill share**

    a. Everyone brings experiences and skills to your team, and this includes partners. Ask team members to teach everyone their skill on a video call as a team-building event.

    b. The best way to find out about skills your team members may have is to just ask. After discussing parts of the project that need to be completed, ask if anyone has the skills to do it.

6. **Create a shared language.**

    a. Learn to communicate to the level of partners. Partners may have some training but will need time and information given to them in an appropriate manner for their level of understanding.

    b. The use of lingo and jargon can be both confusing and intimidating to patient/caregiver-partners. This is particularly important to consider as we think about partners' comfort contributing to the team. Defining acronyms like CFLN (CF Learning Network) as you speak and providing a list of acronyms partners can refer to can ensure all team members understand what is being said. The PCOR champion should also check in with partners regularly to make sure they understand everything.

    c. Foster a culture of questioning. Take the time to answer partner questions about an acronym or concept they don't understand, either verbally or in the chat box of your video conference software. If you won't have time to go over it, the PCOR champion can meet with the partner after to ensure they understand everything.

Generating a Governance Document

A governance document should include the following:

1. A Team mission statement
2. Guidelines about creating inclusive and respectful space (i.e. meeting ground rules)
3. Agreement on how the team will communicate -- this includes video conferencing software, document sharing platforms, instant messaging, email, etc.
    a. See our User Guide on the types of platforms and how to pick ones that meet your team's needs at https://familymedicine.uw.edu/pcor-guide/
    b. Identify a member to serve as a tech lead
4. Address hierarchy and create a level playing field (this includes things like being on a first name basis)
5. Sometimes people with CF get sick and team members have to be flexible when medical issues come up

Consider: The first line of an agreement should be that the team will honor partners' health

6. Frequency and length of meetings
7. Identify areas where patient/caregiver-partners will take a lead in activities (such as publishing in non-peer reviewed publications)
8. Discuss partner and other stakeholder compensation. Given the institutional barriers at the funding researchers' institution identified under the Prepare phase.
9. Evaluation
    a. Discuss how frequently you will evaluate the team dynamic
    b. Discuss if team members have other components they would like to evaluate.

HELPFUL HINT

Create processes up front to allow for make-up work, a meeting surrogate, or other ways the team can move forward without leaving the person taking time for their health behind.

This is considered a living document, and one that the group should re-visit on a regular basis. Make sure that all stakeholders have an opportunity to discuss and comment on the group vision, mission, philosophy, outcomes, expectations and roles

Sample Stakeholder Engagement Plan

Below is an example of how partners can participate on research teams at different levels of engagement. The table also outlines how partners can be compensated, depending on their level of engagement.

Engagement level	Participant Role	Responsibilities	Compensation
Occasional	Any interested person with CF	• Give occasional feedback on CF project ideas and progress; • Chat on public Facebook page, or answer online surveys. • Vote on priority areas for research.	None
Medium	Engaged researchers, consultants, and other stakeholders	• Meet with research team to discuss patient research questions. • Help translate these questions/ideas into fundable research questions. Provide feedback on the CF project progress. • Provide ideas for how to reach the greater CF community.	$20/meeting
High	Equal partner	• Drive overall direction and vision of the project. • People with CF help generate research questions. • Meet regularly during CF project. Provide input on grant applications. Attend regular project meetings, provide input into recruitment plans & materials, how to display research findings. • Help disseminate findings to CF community.	$30/meeting

CF PCOR Training Manual

Step 3: Implement

Once a team has been established, the team is ready to move forward with developing research questions, writing grant applications and conducting funded studies together. We have found that having a research coordinator with excellent communication skills to help coordinate between researchers and partners is key to high-functioning PCOR collaborations.

For the purposes of this document, when the term "partner(s)" is used, it is inclusive of patient and caregiver-partners.

Implement Includes:

1. Planning the study
2. Conducting the study
3. Disseminating the results

The PCOR Champion can use this guide to help the research team integrate new partners in all phases of the research by identifying opportunities where partners can work independently outside of meeting times.

Figure 1. Diagram of the phases of a study

This table of contents is a starting list for this stage, which you can adapt for your needs.

Implement Activities

PLAN THE STUDY

Think about what your study question will be, making final decisions after speaking with your partners. Find out what research questions and outcomes are most important to the community.

Ways partners can engage while planning the study:

01 Identifying the research question

02 Identifying outcomes

03 Providing input into the study design

04 Creating a dissemination plan

The first thing to do when planning a study is to brainstorm ideas with a diverse set of partners. Our team's preferred way of doing that is by hosting World Café discussion sessions on the research team's area of interest to gather a list of questions that are most important to patients/caregivers.

World Café is a process of consensus building, achieved through collaboration between stakeholders. Partner/researcher duos host rooms and discussions with prompts meant to spur conversation and ideas. The goals for duos are to find the questions and outcomes that matter most to partners. In person, this is achieved through having multiple tables with no more than 4 people, accompanied by large sheets of paper and markers. A similar impact can be achieved virtually by using online tools such as mural at https://www.mural.co/ or by using the whiteboard function on Zoom.

Follow these steps for a World Café session:

1. Use researcher/partner duos to design the discussion questions and lead the groups. Example questions are available at https://academic.oup.com/jamia/advance-article-abstract/doi/10.1093/jamia/ocab224/6408574
2. Invite 10-15 additional patient and/or caregiver attendees to participate in discussions to identify research questions and study outcomes. Attendees can be recruited from CFF Community Voice.

   Note: There will be more patients and caregivers participating at this stage than on your PCOR team, but a group of this size will help you to gather diverse input. If your PCOR team does not already include the number of partners desired, this session is also an opportunity to determine the interest of and recruit partners.
3. Allow attendees to reflect on all of the ideas generated during the discussion session and prioritize top research ideas and outcomes for the research team at the end.

Formulate Research Questions and Outcomes That Reflect Patient-Driven Priorities

Taking the priority list from World Cafe or other brainstorming techniques, the research team (including partners) can then translate partner ideas into fundable research question(s). Please refer to the supplement "Turning Partner Ideas Into Fundable Questions" on page 49. In the table below, we present three patient-identified topics (left column) related to reproductive health in CF and how researchers and partners together turned them into fundable research questions (right column):

Turning Patient Ideas Into a Research Grant

Patient-Identified Topic Area	Fundable Research Questions
Parenting and pregnancy decision making	• What is the impact of lung function on pregnancy? • What is the impact of lung function over time after pregnancy? • What does parenting with CF look like?
Perimenopausal/menopausal stage of life	• Is it safe/beneficial for women with CF to take hormone therapy after menopause? • Do women with CF enter menopause earlier than women without CF?
Contraceptive use and CF	• How does hormonal birth control interact with CF medications? • What are the long-term effects of hormonal birth control use on women with CF?

Table 1. Examples of patient ideas turned into fundable research questions

HELPFUL HINTS

Sometimes patients and caregivers provide research ideas that are not feasible. In this case PCOR champions must explain why a particular question is not feasible. Help engage the partners in reframing the question so that it is succinct and measurable. Alternatively, PCOR champions and other research team members may have their own research questions they want to pursue that don't align with what the CF partners prioritize. PCOR champions and researchers should be prepared for some flexibility around research questions they submit for funding, potentially including those prioritized by CF partners.

Write The Grant

Grant writing usually requires a flurry of activities that may be unsettling to partners. Set expectations about grant writing early.

Clarify roles prior to writing the grant

- Most of the grant writing is likely to be completed by the Project Lead and research team members, with partners serving as advisors.
- The Project Lead should decide whether the partners can take a lead on one or more pieces of the grant writing, such as dissemination of findings to the CF patient or caregiver community.
- Grant applications should include a stakeholder engagement activity plan as part of the research study. See the "How to Write an Engagement Plan" supplement on page 51.

After writing a grant, a partner wanted to understand the process more fully because not all components they wrote were incorporated into it, or they were changed by the Project Lead. The partner was surprised, and even a bit hurt. The Project Lead met with the partner to review and explain some of the changes that were made in the writing. The meeting helped the partner understand the grant process and improve their grant-writing skills. The meeting also led to greater satisfaction with the process and team relationship. As the team wrote more grants, the Project Lead preemptively explained changes in the grant application, which led to meaningful discussions with the research team explaining their contributions and edits to the grant application.

Here is a list of ways Project Leads can help keep partners engaged during grant writing and set expectations about when teams hear back about funding and likelihood of funding:

1. Identify parts of the grants that a patient/caregiver-partner may be able to write. Patient/caregivers know their community well and often can give important feedback about how best to recruit research subjects or how to disseminate the results.
2. Consider having a research coordinator work closely with partners on certain sections of the grant such as how partners will be engaged in the project.
3. Check back regularly with partners about the progress of the grant submission. Let partners read parts of the submission with the understanding that the Project Lead may choose not to implement all the feedback. *Make sure to communicate realistic expectations to partners.*
    a. Patients and other stakeholders are often unaware of the time it takes to hear back about a grant, only to find out it was not funded. It is imperative that you share these possibilities with your team. A funding rejection can be discouraging, but if possible, turn this into a positive learning experience that the team can grow from. This will help to make it feel less like a loss.
    b. Consider applying to multiple places for funding.
4. Partners are often key players in the grant, so it is important that the Project Lead sets the expectations early and can plan for other smaller grant activities for the team to work on while waiting to hear back about another grant.

Writing an engagement plan

Many grants in which partners are written into a research team require an engagement plan. An engagement plan spells out most items in your team agreements (see Launch Guide), including when and how your team partners will be engaged within each phase of the study.

How to write an engagement plan:

- Provide a roster of organizational stakeholders or individuals who are advising the study team (include 3-5 sentence bios)
- Articulate the structure of your engagement with patients and caregivers, including communication plans (see Launch section)
- Provide an activities timeline that includes descriptions of researcher/ partner activities, frequency, and purpose (see Stages of studies and potential partner activities table below.)
- Outline how often the team plans to meet

If you're unsure about an engagement plan structure or details, a great place to start is PCORI's Engagement Plan Template at https://www.pcori.org/sites/default/files/PCORI-Updated-Engagement-Plan-Template.pdf. For examples, see the "Sample Stakeholder Engagement Plan" supplements on pages 52-54.

The following table outlines examples of activities partners may participate in at all phases of research

Study Stages	**Activities of Patient/Caregiver Partners**
Pilot	• Review pilot results and provide feedback for changes to the study • Review survey questions and other data collection forms
Data Collection and Enrollment	• Help create and post recruitment flyers • Receive updates about enrollment progress and advise as needed • Present updates about progress of research study to health care providers and patients/families/community
Analysis	• Discuss interpretation of findings and the study's conclusions • Provide input about how to best present the study findings so they are understandable to a wide audience • Patients may participate in qualitative analysis (this may require additional training)
Dissemination	• Create compelling and understandable summaries of research and findings for patients/families/community • Identify organizational groups/committees and community groups that should be informed about study findings • Help write and edit publications for peer-reviewed journals • Present findings to health care providers and patients/families/community

Table 2. Stages of studies and potential partner activities.

Debrief about the grant writing process after submission

- Gather feedback from team members (researchers and partners) after the grant is submitted
    - ◊ Send a confidential survey or host a meeting to discuss what worked well/didn't work well with the grant writing process.
    - ◊ Incorporate feedback before the team writes their next grant.
    - ◊ Communicate what you improved upon from your last grant, so team members are aware of changes.

CONDUCT THE STUDY

Once the grant is funded, the team can get to work.

Help The Team Stay on Track to Complete The Grant Project on Time

Ways partners can engage while conducting the study:

01 Assisting with data collection

02 Advising on study participant recruitment and retention strategies

03 Developing the study materials

04 Advising on how to present findings for lay audiences

- Meet regularly with the whole research team, including the partners. As regular and engaged partners, research teams benefit from novel input.
- Create a detailed plan of tasks with due dates.
- Review the timeline regularly and adjust accordingly.
- Consider using project management tools.
- Keep in mind that getting behind on project tasks or milestone deadlines can be stressful for partners because often their schedules do not allow for "quick turn-arounds" or "working until the work is done."
- Be open to the tasks partners can undertake that had not been considered in early planning.

Tips to help teams organize their projects:

- Use the PRINCE2 method to help with the organization and control of projects. It is not specifically designed for research studies, but can be tailored to fit your study's needs. PRINCE2 Training options are found here: https://www.prince2.com/uk
- Other tools for keeping your study on its timeline and managing tasks include using a Gantt chart or other technologies through websites and programs such as smartsheet at https://www.smartsheet.com/s/pm-templates-gallery and click up at https://clickup.com/project-management/task-management.
- If you introduce new tools for the team to use, make sure every team member has been oriented to how to use those tools.

Ways to avoid getting delayed:

- Think ahead about potential roadblocks: which roadblocks might occur and what strategies will the Project Lead suggest to handle them?
- Include "padded" time for parts of study that may take more time (plan to start the more difficult aspects of the project earlier than what the grant timeline may have proposed).
- Determine if tasks can be shared.
- Facilitate team members directly talking to one another if one team member needs information from another.

DISSEMINATE THE RESULTS

Ideally teams have already considered their dissemination plan during the planning phase.

As the study progresses, the PCOR team can build out their plan for dissemination using the "Dissemination Tool" supplement on page 54. The tool asks PCOR teams to consider:

- Primary, secondary, tertiary communities they would like to reach.
- How messages will be tailored to each community.
- Ways in which they plan to reach those communities.

Review the PCORI website for examples about how to create a story about your findings: "PCORI Stories" at https://www.pcori.org/impact/pcori-stories. PCORI includes written and video testimonials from both patient partners and researchers.

- Consider disseminating your research using audio at https://www.pcori.org/research-results/pcori-stories/changing-conversation-about-intellectual-developmental-disabilities and video at https://www.pcori.org/research-results/pcori-stories/engagement-awards-teams-ride-momentum-research-projects from partners who participated on study teams.
- Examples of PCORI researchers who have shared their content can be viewed here, https://www.pcori.org/research-results/pcori-stories/spreading-communication-plan-improve-patient-safety-hospitals and at https://www.pcori.org/research-results/pcori-stories/using-personal-health-characteristics-to-develop-individualized-and-personalized-treatment

Ways partners can engage while disseminating results:

01 Co-authoring and/or co-presenting findings at scientific conferences

02 Co-authoring manuscripts for scientific journals

03 Writing articles in community publications

04 Posting published papers in community forums, blogs, and facebook groups

05 Helping with other activities identified in the dissemination plan

Recognizing the involvement of patient/caregiver stakeholders in scientific publications is key to building and maintaining trustful relationships.

- Partners can write up the study in non-peer reviewed publications such as CF Roundtable, CFF Community blog, and CF News Today, or post about it on social media.
- For an extensive review about dissemination please see this PCORI document at https://www.pcori.org/sites/default/files/PCORI-DI-Toolkit-February-2015.pdf

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Our CF PCOR team conducted a survey study to examine what health care providers, patients, caregivers and other advocates thought about patient-centered outcomes research. As data collection and analysis were underway, the PCOR team discussed the different communities that may be interested in the findings. They used the Dissemination Tool to identify their primary and secondary audiences. Partner members had ideas about how to post study findings on blogs or social media platforms and who would be the primary team member to disseminate those findings. The team made plans for researchers and partners to submit poster presentations and present as a duo. The researchers prioritized peer-reviewed publications, while the partners identified community- specific publications they would take the lead to write in.

You have reached the end of Implement section

Implement Supplement

Turning Partner Ideas Into Fundable Questions

This tool provides additional instructions and guidance to help you complete a Comparative Effectiveness Research (CER) Question. CER compares one type of treatment to another. CER is frequently used in PCOR. This tool is based off the PICOTS framework (Population, Intervention, Comparators, Outcomes, Timeframe, and Setting). More information about PICOTS can be found in this article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3430448/. Much of your future work should focus on using the PICOTS framework and we highly encourage you to share the article link above with your project partners as you work on your research questions together.

CER Question	Write your CER question here. Then describe the details in the lines below. Be sure to use PCORI's guidelines for writing research questions: http://www.pcori.org/get-involved/suggest-patient-centered-research-question/how-write-practical-useful-research-question.
Population	***What is the patient population of interest?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Are intervention effects expected to be homogeneous or heterogeneous between different subgroups of the population? What subgroups will be considered in terms of age, gender, ethnicity, etc.? How will patients be recruited for the study?
Intervention	***How will your CER question and study translate into meaningful real-world situations?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Is your intervention evidence-based? How will patients access the evidence-based intervention? What will the costs of the evidence-based intervention be? Who will implement the evidence-based intervention? Why is your study design the best way to answer your CER question?

Comparator	***What are the alternatives?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Why are these comparators the best for your patient population? What benefit does each comparator provide? What data proves the efficacy of each comparator? What modifications to each comparator might make them more appropriate for the population of interest? How will a study of these comparators help patients make decisions in the healthcare system?
Outcomes	***What are the outcomes and endpoints of interest?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Why are these outcomes important to your patients? What will the impact of these outcomes be in the health care system? How will you measure the outcomes? How will you share your findings with the research, patient and stakeholder communities?
Timing	***What is the time frame needed to implement the evidence-based intervention and assess outcomes?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Are stakeholders interested in short-term or long-term outcomes? Why is this an appropriate time frame for your patient population? Is the time frame realistic for the funding period and budget? Why is the time frame realistic for getting to robust research outcomes?
Setting	***What is the setting of interest (e.g., hospital, private practice, community, etc.)?*** Prior to identifying your CER question(s) you should be able to answer the following questions: Why is this an appropriate setting for your patient population? How is the setting appropriate for the time frame and budget? How is the setting realistic for translating outcomes into a real world setting that is meaningful to patients? How is the setting the most appropriate place to conduct this research?

Example: Key Activity Timeline

Meeting Activity	Frequency	Setting/Method	Purpose
Fill in the meeting or type of activity taking place	Fill in the frequency of ether the meeting o activity (e.g., monthly, quarterly, as needed).	Detail the setting for meetings of the methods for the activity	Write about the purpose and intent of the meeting or activity
e.g., Community Advisory Board Meeting	e.g., Quarterly	e.g., Community public library in person	e.g., Year 1: input on protocol development, finalizing outcome measures; Year 2: recruitment strategies; Year 3: Data analysis and dissemination
e.g., Patient/Caregiver Advisory Board	e.g., Monthly for the first 6 months, then quarterly, with an annual combined meeting of entire study team	e.g., Monthly and quarterly meetings on Zoom web conference platform; Annual meetings in person at varying locations, one year at Medical Center, one year at community based organization.	e.g., First 6 months: refine study protocol and outcome measures. Quarterly: provide project status updates including preliminary data analysis, recruitment challenges, refinement of patient-facing materials Annual: shared decision making on larger study design and implementation issues, dissemination planning, preliminary data analysis

Adapted from: https://www.pcori.org/sites/default/files/PCORI-Updated-Engagement-Plan-Template.pdf

Sample Stakeholder Engagement Plan for Grant Applications

The table below is an example of how stakeholder engagement can be outlined in a grant application. It includes the level of engagement, activities and compensation.

Engagement Level	Participant Role	Responsibilities	Compensation
Occasional	Any interested person with CF	• Give occasional feedback on CF project ideas and progress; • Chat on public Facebook page, or answer online surveys. • Vote on priority areas for research.	None
Medium	Engaged researchers, consultants, and other stakeholders	• Meet with research team to discuss patient research questions. • Help translate these questions/ideas into fundable research questions. Provide feedback on the CF project progress. • Provide ideas with reaching the greater CF community.	$20/meeting
High	Equal partner	• Drive overall direction and vision of the project. • People with CF help generate research questions. • Meet regularly during CF project. Provide input on grant applications. Attend regular project meetings, provide input into recruitment plans & materials, how to display research findings. • Help disseminate findings to CF community.	$30/meeting

Sample Stakeholder Engagement Plan From Cystic Fibrosis Reproductive and Sexual Health Collaborative (CFReSHC)

Who?

The table below lists organizational stakeholder partners with whom CFReSHC will collaborate

Source	Type	Address	Website	Program, Service or Activity
Cystic Fibrosis Foundation	National	Bethesda, MD	www.cff.org	Community and Research Voice Initiatives
Cystic Fibrosis Research, Inc.	National	Redwood City, CA	www.cfri.org	Annual Conference
Cystic Life	National	Arizona	www.cysticlife.org	Online community

Why?

Source	Why we are engaging with this stakeholder organization?	Anticipated benefit of engagement?
Cystic Fibrosis Foundation	The CFF has multiple resources for CFReSHC, including: 1. Opportunities to hold mini-conferences for members with CF 2. Opportunities to apply for funding 3. Has a CF Adult and Family Advisors Group, which consists of over 500 members	1. CFReSHC patient partners are organizing and hosting a mini-conference about sexual and reproductive health for patients with CF. This is the crux of our Collaborative and a much desired topic for which women with CF would like more information about. 2. Several of our Research Advisory Panel members have funding from CFF and through their projects are advancing the mission of CFReSHC. We have had conversations with CFF about additional funding for sustaining and advancing our CFReSHC work. 3. We hope to use the Advisors group to get feedback on research ideas generated by our Patient Task Force, or to disseminate new findings or workshops we generate through CFReSHC
Cystic Fibrosis Research, Inc.	1. Weekly e-blasts 2. Had a pod cast on contraception and women's health topics in 2017 by a provider at Stanford 3. National Conference that allows patients with CF to attend	1. We hope to use e-blasts to disseminate new findings or workshops we generate through CFReSHC 2. CFRI has an interest in CFReSHC stated topic. We hope to recruit more interested members into CFReSHC through CFRI
Cystic Life	1. Well established on-line community with CF patient, caretakers and advocates.	Enhances our lines of communication with the greater CF community

How?

Source	Contact Person	Role we hope stakeholder will play in CFReSHC partnership?
Cystic Fibrosis Foundation		
Cystic Fibrosis Research, Inc.		Provide avenue for dissemination, help CFReSHC recruit more members
Cystic Life		Provide avenue for dissemination of our findings or activities to the greater CF community.

Dissemination Tool

<Project title>

Project Background				
Project Objective				
Project Findings (brief)				
PRIMARY TARGET AUDIENCE:				
OUTREACH PURPOSE				
PRIORITY POPULATION 1	KEY MESSAGES & CONTENT	DISTRIBUTION CHANNELS	RESOURCES REQUIRED?	RESPONSIBLE PARTY?
	Key Message 1:			
	Key Message 2:			
	Key Message 3:			
PRIMARY TARGET AUDIENCE:				
OUTREACH PURPOSE				
PRIORITY POPULATION 2 (OPTIONAL)	KEY MESSAGES & CONTENT	DISTRIBUTION CHANNELS	RESOURCES REQUIRED?	RESPONSIBLE PARTY?
	Key Message 1:			
	Key Message 2:			
	Key Message 3:			
SECONDARY TARGET AUDIENCE:				
OUTREACH PURPOSE				
PRIORITY POPULATION 1	KEY MESSAGES & CONTENT	DISTRIBUTION CHANNELS	RESOURCES REQUIRED?	RESPONSIBLE PARTY?
	Key Message 1:			
	Key Message 2:			
	Key Message 3:			
SECONDARY TARGET AUDIENCE:				
OUTREACH PURPOSE				

PRIORITY POPULATION 2 (OPTIONAL)	KEY MESSAGES & CONTENT	DISTRIBUTION CHANNELS	RESOURCES REQUIRED?	RESPONSIBLE PARTY?
	Key Message 1:			
	Key Message 2:			
	Key Message 3:			
TERTIARY TARGET AUDIENCE:				
OUTREACH PURPOSE				
PRIORITY POPULATION 1	KEY MESSAGES & CONTENT	DISTRIBUTION CHANNELS	RESOURCES REQUIRED?	RESPONSIBLE PARTY?
	Key Message 1:			
	Key Message 2:			
	Key Message 3:			

CF PCOR Training Manual

Step 4: Monitor & Sustain

The Monitor & Sustain guide provides suggestions for supporting success and implementing continuous improvement. The guide contains examples of surveys that the team can disseminate to gather information about how the researcher/stakeholder relationship is going, whether equal partnership is being maintained, and where teams may need to adjust to improve their processes.

For the purposes of this document, when the term "partner(s)" is used, it is inclusive of patient and caregiver-partners.

Monitor and Sustain includes:

1. Supporting the PCOR team
2. Evaluating engagement
3. Handling disagreements
4. Continuing engagement

This table of contents is a starting list for this stage, which you can adapt for your needs.

Monitor Activities

SUPPORTING THE PCOR TEAM

PCOR champions should continuously support the PCOR team throughout the project. To do so, consider implementing the following:

- Frequently review the team's mission statement and project goals.
- Review meeting team agreements before every meeting (For ideas for creating meeting team agreements, see the "Sample Meeting Ground Rules" supplement on page 62).

Further, during all interactions with the team, champions should:

- Apply best practice guidelines for participation in meetings and other team interactions (see "Agreements for Meeting Behavior" supplement on page 63).
- Encourage team members to assume any contribution has a positive intent.
- Recognize potential tension between productivity and inclusion:
    - ◊ Stay focused on getting tasks done and meeting milestones, but be flexible when things change, such as a partner being out with illness or taking care of an ill family member.
    - ◊ Take into account partner needs and inputs.
    - ◊ While partners strengthen the project, recognize that adjusting elements of the research project based on partner feedback takes time and can slow down the research process.
- Lead by example – treat others with mutual respect.
- Continually find ways to reduce hierarchy.

HELPFUL HINT

PCORI has recommendations for best practice guidelines for participation when speaking in front of the group. These include:

1. **Use I-statements (e.g., I think, I believe)**
2. **State your goal**
3. **Pros and cons to your point of view**
4. **Contextualize (where is your point of view coming from?)**

EVALUATING ENGAGEMENT

Having a system in place to regularly evaluate the PCOR engagement process is critical to team sustainability.

Consider Including a Process Evaluator

This could be anyone on your team or a consultant/ambassador who has experience with PCOR.

Team evaluation can occur in the following ways:

- Process evaluation measures your project progress and efficacy.

- Consistent project evaluation can help your team discover problems before they arise and help you to redirect when they do.
- A process evaluator will help your team determine if your study is having the effect you intended.
- Process evaluation helps determine if your study is reaching the correct population and if you are having the results you hoped for.
- For more information about process evaluation and methods of process evaluation for community-based teams, review this article: https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.27.021405.102207
- Distribute a confidential stakeholder/partner survey at regular intervals.
  - ◊ For smaller research groups, see example stakeholder survey questions in the "Example short stakeholder survey for small groups 1/2," located on pages 64 and 65.
  - ◊ For larger stakeholder groups, and groups with diverse stakeholder members, see the "Example Extensive Partnership Survey for Large Groups" supplement, starting on page 66.
- Have regular one on one check-ins with partners.
- Be able to respond and change course to improve experiences.
- Evaluate the meeting at the end, every time, such as through the Whip Method (explained below). Feedback can be provided verbally, written, or through another method that works best for the PCOR team.

HELPFUL HINT

Establishing a process in which to assess partnership is important. An increasing number of publications with studies that include partners are asking authors to articulate the impact of partner engagement and how this impact was evaluated. Publishers also expect to see critical reflections from researchers about what went well or poorly with partners on the team.

Assess Inclusion

Part of evaluation is assessing for inclusion. PCOR champions want to ensure that diverse voices of all partners are heard. Below are some questions you can ask partners to assess for inclusion:

- How has your unique perspective been incorporated?
- Have you felt heard?
- Have you been treated as an expert of your own experience?
- How do you think your participation has changed or enhanced the project?

HELPFUL HINT

The Whip Method is a form of evaluation at the end of meetings. The Whip Method asks participants to reflect on what went well, what went poorly, and their feelings throughout the meeting. After this brief reflection, everyone on the team is asked to sum up how they felt about the meeting in one word. This method of feedback can help you gauge your team's engagement and energy. An example of the Whip Method can be found at this link: https://www.leadstrat.com/dysfunction-prevention-technique-bring-the-whip-to-your-meeting/

HANDLING DISAGREEMENTS

Over time, friction can occur between members on your team, as it does on any team.

- Plan ahead: PCOR champions should talk to team members privately to find out how they react to discord as individuals (see Thomas-Kilmann information below). This will help the PCOR champion to be better equipped to facilitate a productive conversation and help contain conflict on the team.
- Natural disagreement must be dealt with openly and often, with the goal of turning disagreement into productive learning and negotiation. Use it to help create common understanding for the partnership.
- Disagreements can bring new information or a reframing of an idea, issue, or course of action, which may help your project move forward.

HELPFUL HINT

Thomas-Kilmann Conflict Mode Instrument gives 5 styles for handling conflict, including collaborating, avoiding, accommodating, competing, and compromising. The PCOR Champion should be aware of their conflict handling style, as well as those of members on your team. It will help them determine when to use each and how they handle conflict personally. Note: disagreement should occur for the betterment of the study, but avoid personal attacks. https://www.researchgate.net/profile/Ralph-Kilmann/publication/265565339_Thomas-Kilmann_conflict_MODE_instrument/links/558c15d908aee43bf6ae1917/Thomas-Kilmann-conflict-MODE-instrument.pdf

What To Do When There Are Conflicting Opinions:

- Help team members think critically
- Reframe the disagreement
- Ask members to back up their thinking with reasonable arguments
- Recognize that disagreements cannot necessarily be resolved in a single team meeting
- If disagreements persist, consider bringing in a mediator, either from your university or someone outside to help the team work through it and avoid resentments

HELPFUL HINT

Disagreement, whether it is dissenting opinions, world views, or personalities can be frightening to people, and thus, they do their best to ignore or gloss over it. PCOR champions should be ready to bring conflicting opinions in the open and discuss them. Encourage team members to resolve their differences by learning from each other and putting their ideas together.

A partner felt frustrated with a lack of communication and information sharing by the team. After some tense team discussions, they decided to bring in a mediator from the university. The mediator met with the team and helped resolve the conflict. All members of the team were satisfied with the mediation and the work was able to proceed without further conflict.

CONTINUING ENGAGEMENT

Celebrate Successes

- Review and celebrate processes that are going well within the PCOR team
- Encourage partners to write about team successes with their respective communities such as CF Roundtable, CFF community blog, CF News Today, and post links on social media. Tag well-known CF accounts in posts and ask them to cross-post
- Always send thank-you letters when you receive support—no matter the type of support, large or small
- Communicate regularly with your stakeholders so that they understand the value and impact of their support

Evolving Partner Roles

HELPFUL HINT

As your team moves forward, the role of partners may evolve. You may find that some partners leave the project due to a change in health or circumstance and thus, the team may need a replacement. The team also may expand and include new, additional partners, budget allowing. For partners who leave the team, think about following up personally to find out why. It is helpful to check in with partners who have missed meetings without notice to understand whether the current arrangement is meeting the needs of the partner. Partners may also want to stay involved with the team, but in a less-committed role as an advisor instead of partner. (See levels of engagement in the Prepare Section)

Expanding the Partnership

One way to recruit new partners onto the research team is to ask the current partners to help invite, interview, and select new partners. You may find if your team has been in place for some time, it can be difficult to onboard new partners. Make sure to review "Onboard Partners" and "Create a Welcoming Environment" in the Launch Guide when new partners join the team.

At these junctures, revisit team agreements and norms to ensure new partners understand how the team currently functions. This gesture also provides your new partner an opportunity to describe how they would like to participate on the team.

Another idea is to pair an established partner with the new partner as a "buddy." This can help make them feel welcome and comfortable on the research team. The buddy can check in with new partners, speak to them between meetings, and help explain what the study is and their role on the team.

Planning Future Grants

Before the study is finalized, the team should take some time to think about whether they want to continue working together on future funded projects. It often makes sense to continue with the same team and partners due to the amount of time and expertise that went into building trustful, productive relationships. Some questions PCOR Champions should consider to assess future plans include:

- Are there additional patient-directed research questions that warrant further study?
- Do the current partners have the interest, capacity, skills for the next grant?
- Do research team members and partners see the value of co-production between researchers and partners to build ongoing collaborations to meet the PCOR team's objectives?
- Is the team able to study the impact of partner engagement on research findings?

Even if the team is not continuing with another project together, partners often stay involved as co-authors when manuscripts are submitted, which can be months after the project concludes.

HELPFUL HINT

When a project ends or a partner leaves the project, make sure to thank them for all their time, effort, and expertise. You can send them an e-card signed by everyone on the team, or a handwritten thank you note, or something else to show your appreciation.

You have reached the end of our CF PCOR Training Manual

Example Meeting Ground Rules

Ground Rules for Meeting Logistics

1. **Send out the agenda in advance.** The meeting planner should prepare and distribute the agenda and pre-work before the meeting takes place. The agenda should be sent out 5 days in advance. Documents for review should be sent out a week in advance. Keep the meeting focused on moving through the agenda items.
2. **Include timestamps on the agenda.** The meeting planner should include how much time each item is expected to use, in order to keep the meeting running smoothly.
3. **Assign virtual meeting roles.** Assign a note-taker, time-keeper, and facilitator for all your virtual meetings. Rotate roles each meeting; create a calendar a few meetings in advance to keep track of roles. Facilitator should be mindful of cultural/ language differences and group dynamics, while also asking relevant questions and managing time.
4. **Follow the agenda template**. Write out meeting objectives at the top of the agenda. Clearly mark which agenda items will require information sharing, information gathering, or making a decision.
5. **Start with the most important items**. The agenda should include the most time sensitive or pertinent items early in the meeting to ensure there is sufficient time to discuss.
6. **Remind participants of rules for meeting behavior.** The facilitator should briefly state the ground rules for meeting behavior at the top of the meeting.
7. **Start and end meetings on time and arrive at meetings punctually.** Respect each other's time. Start on time even if all participants are not present.
8. **Prepare adequately for the meeting and participate fully.** Meeting attendees will have read, reviewed or examined pertinent documents, gathered information or input, or simply assessed our own thoughts and ideas prior to the meeting. Our team will accommodate accessibility requests from the group to ensure that everyone can participate fully.
9. **Debrief at the end of the meeting.** Conclude the call by summarizing, confirming decisions, reiterating next steps, and having all participants rank the meeting on a scale of 1 (poor) to 5 (excellent). Discuss any ratings of 3 or lower.

Agreements for Meeting Behavior

1. **Treat everyone with respect**. We will express our opinions responsibly, focusing on the issues and not on personal differences, and speak both honestly and kindly.
2. **Not interrupt each other**. We recognize that we all sometimes interrupt, either by mistake or to build on others' statements. However, we will strive to allow each person the space to finish his or her thoughts.
3. **Express ourselves completely and concisely**. We recognize the value of each other's input and time.
4. **Engage with each other's thoughts, ideas and opinions.** We recognize the value and richness of a meeting when everyone has a chance to participate. We will graciously engage with opinions different from our own.
5. **Stay focused on the topic under discussion.** We will stay focused on the agreed upon topics unless the group makes a conscious decision to alter the agenda.
6. **Intervene immediately if you believe things are running off track.** We are all empowered to gently and firmly intervene if another participant is off-topic or acting out of sync with the ground rules. For example, the facilitator may choose to send someone a private message during the meeting if they believe that someone is leading the meeting off track.
7. **Do not multitask** (do other work) during the meeting.
8. **Use the mute button** when you are not speaking to prevent the transmission of background noise.
9. **Speak up** or comment in the chat box to get attention if you have something to say.
10. **Turn on your video** whenever possible.
11. **Say hello** and introduce yourself if you are calling in and we cannot see your face.

Example Short Stakeholder Survey for Small Groups 1

Please state your agreement with the following statements:

1. Team members in the group respected my opinion

Mark only one oval.

	1	2	3	
Agree	○	○	○	Disagree

2. I spoke up as much as I wanted to in the group

Mark only one oval.

	1	2	3	
Agree	○	○	○	Disagree

3. There was enough time to discuss all the relevant issues

Mark only one oval.

	1	2	3	
Agree	○	○	○	Disagree

4. The facilitator ensured that all opinions were considered

Mark only one oval.

	1	2	3	
Agree	○	○	○	Disagree

5. I understood the issues well enough to participate as much as I wanted to

Mark only one oval.

	1	2	3	
Agree	○	○	○	Disagree

Example Short Stakeholder Survey for Small Groups 2

1. Have you received all of the information you would like to receive about the current research project?

2. Have you been able to provide all of the feedback that you would like to share about the current research project?

3. Has the research team adequately responded to the feedback you have shared?

4. How would you describe your role on this project to others?

5. How has your experience so far compared to your expectations?

6. How can we improve our ability to incorporate your knowledge and recommendations into current and future research?

7. For each of the following types of communication, please indicate if you would like more or less:

• Meetings	More frequent	Same	Less Frequent
• Emails	More frequent	Same	Less Frequent
• Telephone	More frequent	Same	Less Frequent
• Other (please specify):	More frequent	Same	Less Frequent

8. Please share any other comments you have about this experience and how we can improve it.

Example Extensive Partnership Survey for Large Groups

Background:

To help you diagnose the health of your partnership and its progress through the PCORI Pipeline to Proposal process, we offer this easy-to-use Partnership Assessment Survey. The assessment was developed by the Colorado Foundation for Public Health and the Environment and uses components of assessments developed by Community Development Consultants of New York City, Health Resources in Action of Boston, MA, and Carl Larson, PhD. It should take around 20-30 minutes to fill out and then as long as your partnership needs to analyze and discuss the results.

Instructions:

Word: If your partnership is technology averse, or would like to fill the survey out together at the meeting, feel free to use the provided document to print out the survey.

At the end of the survey, you can input the corresponding scores for each section into the Total Score box and then use those scores to calculate the percentage for each section. You can then use those scores to make recommendations on where you partnership needs the most work.

Excel: The Excel version of the Partnership Assessment Survey has the advantage of automatically calculating your score. Simply start answering the questions by selecting an option for each question from the drop down menu. You can find the survey on the next tab at the bottom of the screen. Please note that you will not be penalized for answering "N/A - Not Applicable". Once finished, move to the "Results" tab to see your scores. If you missed any questions, they will be highlighted in bright yellow on the scoresheet. We recommend sending the survey out to partnership members before meeting in person so that they have time to fill it out and can come to the meeting with the results ready to be shared, analyzed, and discussed to further the growth of your partnership.

Some things to think about:

- Consider giving the assessment to all researchers, patients, stakeholders, and clinicians in your partnership. Generally speaking, the more the better; get them involved in the maintenance process.
- Review and talk about the results.
- Share the results in a partnership meeting and allow enough time for discussion.
- Consider forming a committee or group to make recommendations to improve your partnership based on the results.
- Vote on any recommendations offered according to the rules of your governance document.
- Follow up regularly to make sure that the approved recommendations are implemented.
- Review and think about re-administering the survey on a regular basis, perhaps once every tier. Ask yourselves: Have the adopted recommendations been carried out? How does this tier's scores compare to the previous tier? Is the partnership moving in the right direction?

Partnership Assessment Survey	Strongly Disagree (0)	Disagree (1)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)	N/A (Do not count)
A. PARTNERSHIP VISION, MISSION AND GOALS						
Taking into account what is happening in our patient community, our partnership periodically reassesses and updates its:						
1. vision statement (your dream)						
2. mission statement (what you're going to do)						
3. goals						
Our health topic local, regional, and national stakeholders (non-partnership members) have been informed of our partnership's:						
4. vision statement						
5. mission statement						
6. goals						
SECTION POINT TOTAL: _________						
B. COLLABORATION/COOPERATION						
7. Projects and activities are culturally appropriate						
8. Our partnership has one or more patients, researchers, and stakeholders who regularly attend meetings						
9. All members are welcome in our partnership regardless of economic status, gender, sexual orientation, race, age, or education level.						
10. Our partnership utilizes the resources and information of other organizations that can help our patient population, such as training workshops						
11. Our partnership utilizes working subgroups, councils, or panels when necessary to accomplish key objectives						
12. There is adequate recognition and compensation for member contributions, both big and small						
SECTION POINT TOTAL: _________						

Partnership Assessment Survey	Strongly Disagree (0)	Disagree (1)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)	N/A (Do not count)
C. PARTNERSHIP STRUCTURE, PROCESSES AND PROCEDURES						
Meeting Organization and Structure						
Our partnership meetings:						
13. Have written agendas and minutes						
14. Use a facilitator						
15. Happen regularly (e.g. monthly, quarterly)						
16. Actively engage all members						
17. Actively engage the diverse skills and backgrounds of its members						
18. Occur at a convenient time and place for most members, especially patients						
19. Have translation services if requested						
Partnership Structure						
Our partnership:						
20. Has a committee structure to implement goals and objectives						
21. Has a plan for how partners are selected and succeed one another						
22. Has a clearly defined plan of action						
23. Has a core planning (steering) group						
24. Has a governance document that is distributed to all members						
25. Has an organizational chart						
26. Has a recruitment plan for recruiting and sustaining members						
27. Has a long-term sustainability plan						
Partnership Processes, and Procedures						
Our partnership has a clear process:						
28. For decision-making (e.g. group vs. leadership)						
29. For problem-solving and conflict resolution						
30. For new member orientation						

Partnership Assessment Survey	Strongly Disagree (0)	Disagree (1)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)	N/A (Do not count)
Our partnership has written expectations/descriptions:						
31. For roles, responsibilities, and participation of members						
SECTION POINT TOTAL: _________						
D. PARTNERSHIP COMMUNICATION STRATEGY						
Our partnership:						
32. Surveys members' interests, needs, and concerns and shares results with the partnership to guide the project						
33. Communicates the partnership's activities/ decisions to all members						
34. Has developed a system for communicating our work, mission, vision, and goals back to the broader patient population/community (non-partnership)						
SECTION POINT TOTAL: _________						
E. PARTNERSHIP EVALUATION						
35. At the beginning of each tier, your partnership reviews the workplan to develop goals and activities to accomplish during that tier						
36. After each project or tier, the partnership evaluates and reflects on how it went to learn from the experience						
37. Your partnership has conducted a skills assessment of its members						
38. Plans of action outline tasks, who will do them, and by what target dates						
39. Your partnership celebrates its achievements						
40. Activities are evaluated in relation to our partnership's vision, mission, and goals						
SECTION POINT TOTAL: _________						
F. PARTNERSHIP MEMBERS						
Our entire partnership:						

Partnership Assessment Survey	Strongly Disagree (0)	Disagree (1)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)	N/A (Do not count)
41. Demonstrates knowledge of the partnership building process						
42. Demonstrates skill in writing proposals and obtaining funding and resources						
43. Encourages collaboration and negotiation						
Leadership:						
44. Has appropriate time to devote to the partnership						
45. Plans effectively and efficiently						
46. Demonstrates flexibility in accepting different viewpoints						
47. Promotes equal status and collaboration among members						
48. Shares leadership opportunities (i.e., rotate the chairing of a meeting between members)						
49. Is adept in organizational and communication skills						
50. Makes a conscious effort to share leadership by developing new Project Co-Leads, especially among patients						
51. Is willing to support the decisions and recommendations of our partnership						
Partnership members (non-leadership):						
52. Are committed to our partnership's mission						
53. Have a variety of resources and skills to offer						
54. Clearly understand their roles						
55. Actively plan, implement, and evaluate activities						
56. Are regularly involved in meetings and/or activities						
57. Feel a sense of accomplishment						
58. Have benefited from participating in our partnership						
59. Level of turnover does not significantly disrupt our partnership's progress						

Partnership Assessment Survey	Strongly Disagree (0)	Disagree (1)	Neither Agree nor Disagree (2)	Agree (3)	Strongly Agree (4)	N/A (Do not count)
SECTION POINT TOTAL: _________						
G. INCLUSION						
Entire partnership:						
60. Divergent ideas/opinions are respectfully expressed and listened to						
61. All populations in our patient population are represented in our partnership						
Researchers & stakeholders in our partnership:						
62. Encourage patients to come up with their own ideas						
63. Display a willingness to accept and nurture patient leadership						
64. Share decision-making with patients and listen to them seriously						
Patients in our partnership:						
65. Have a high degree of trust in each other						
66. Have a high degree of trust in the partnership's leadership						
67. Are given serious work to do						
68. Have full access to information needed to make decisions						
69. Have opportunities to discuss their concerns about group decisions						
70. Can openly discuss their values, mindsets, and underlying assumptions						
71. Have an equal voice in the decision-making process						
72. Are excited about their involvement						
73. Take initiative in working on projects						
74. Are given major responsibilities for specific tasks						
75. Help one another in developing new skills						
SECTION POINT TOTAL: _______						

Survey Section	Total Score	*Total Possible	Percent	*Note – Subtract 4 points from the Total Possible in a section for each time you used “N/A”.
A. Partnership Vision, Mission, and Goals	0	24		
B. Collaboration/Cooperation	0	24		
C. Partnership Structure, Processes, and Procedures	0	76		
D. Partnership Communication Strategy	0	12		
E. Partnership Evaluation	0	24		
F. Partnership Members	0	76		
G. Inclusion	0	64		
Total of All Sections	**0**	**300**		

If you scored between:

0% – 49.9% - Uh oh! Your partnership needs an overhaul on this section.

50% – 79.9% - Close! Take a look at each question in this particular section to see how you might improve.

80% - 100% - Congratulations! Your partnership is running smoothly. Keep up the good work!