Engagement Rubric for Applicants

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General Guidance

- The Engagement Rubric illustrates how input from patient and stakeholder partners can be incorporated throughout the entire research process. For additional context, consult the "Why Engage?" website landing page and PCORI's Conceptual Framework.
- The Engagement Rubric is intended to provide guidance to those planning or conducting research, merit reviewers, awardees, engagement/program officers (for creating milestones and monitoring projects), and interested patients, caregivers, patient/caregiver organizations and other stakeholders, regarding engagement in the conduct of research.
- The rubric is not intended to be comprehensive or prescriptive. Instead, it provides a variety of options to incorporate engagement, where relevant, into the research process. Applicants using the rubric can choose to include some, but not all, activities and are encouraged to include additional innovative approaches not listed here.
- This guidance is based on the promising practices identified in studies from the PCORI portfolio. It is also consistent with PCORI's Methodology Standards for patient-centeredness and Patient-Centered Outcomes Research (PCOR) Engagement Principles explained below.

PCORI Engagement Principles

As you use the rubric and fill out your Engagement Plan, demonstrate how you espouse the six PCORI Engagement Principles in your work. They are:

- Reciprocal Relationships: This principle is demonstrated when the roles and decision-making authority of all research partners, including the patient and other stakeholder partners, are defined collaboratively and clearly stated.
- Co-Learning: This principle is demonstrated when the goal is not to turn patients or other stakeholder partners into researchers, but to help them understand the research process; likewise, the research team will learn about patient-centeredness and patient/other stakeholder engagement, and will incorporate patient and other stakeholder partners into the research process.
- Partnerships: This principle is demonstrated when time and contributions of patient and other stakeholder partners are valued and demonstrated in fair financial compensation, as well as in reasonable and thoughtful requests for time commitment by patient and other stakeholder partners. When projects include priority populations, the research team is committed to diversity across all project activities and demonstrates cultural competency, including disability accommodations, when appropriate.
- Transparency, Honesty, and Trust: These principles are demonstrated when major decisions are made inclusively and information is shared readily with all research partners. Patients, other stakeholders, and researchers are committed to open and honest communication with one another.

Definitions

- "Patient partners" is intended to include patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

- It is important that patient partners are not confused with patient subjects; patient partners are members of the research team and involved in the planning, conduct, and dissemination of the research, whereas patient subjects are those individuals actually enrolled into the study as participants.
- "Stakeholder partners" may include members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include: clinicians, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions. Some individuals may fit into several categories.

Key Considerations for Planning, Conducting, and Disseminating Engaged Research:

- For the proposed intervention, think through the project from original concept to implementation, and identify the various stakeholders and patients who would need to be included in order for the project to be as successful as possible.

- Think about the budget for your engagement, including compensation for patient and stakeholder partners as well as costs of meetings, IT, and other facilitators of multi-disciplinary work. For additional guidance, PCORI's Compensation Framework provides guidance about how best to compensate patient partners serving on research teams. Additionally, PCORI's Budgeting for Engagement Activities document provides guidance on how to budget for engagement activities.
- Avoid relying entirely on patient partners who have dual roles on the project (e.g., relying on stakeholders or researchers who also happen to be patients). Including at least one patient partner who has no other role on the project is important
- There are myriad ways to discuss and demonstrate engagement in a research proposal including asking partners to provide letters of support, bio-sketches thoroughly describing the roles and decision-making authority of all partners, and clear inclusion of engagement activities and compensation in your budget.

Guidance for Applicants Completing a PCORI Funding Announcement (PFA) Engagement Plan

The Engagement Rubric is divided into three sections; planning, conduct, and dissemination. Each section includes descriptions of the types of activities likely to take place within each phase of research and examples of engagement from PCORI-funded projects. Each numbered section below corresponds to a numbered section in the engagement plan that accompanies each PFA.

1. **PLANNING THE STUDY:** Describe how patient and stakeholder partners will participate in study planning and design. (As you fill out Section 1 of your Engagement Plan, refer to the information below.)

Potential activities include:

- Developing the research question and relevant outcomes to be studied, to ensure that the project and its results will be useful and important to patient and stakeholder communities.
- Defining the characteristics of study participants, to minimize the risk that certain patients will be included or excluded due to criteria that are not relevant.
- Designing the study to minimize disruption to patient and stakeholder study participants, thereby promote retention of study participants.

Real-World Examples:

- Mental health study: Patient partners and community members helped craft the study name and materials to reduce the potential for stigma and to reframe the goal of the study as a movement toward emotional well-being rather than away from a mental health challenge. The anticipated benefit of this input is improved recruitment of study participants and greater acceptance of the study by the community in which it is occurring.
- Large pragmatic study comparing surgery to antibiotics: Over 800 patients were surveyed about their preferences for these treatment options and that input was used to shape the proposal. In this same study, significant clinician input changed the study inclusion criteria, study logistics, and criteria for "failure" for one of the arms.
- Diabetes study: Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly and those changes aim to make the study more reflective of real clinical settings.
- Study on use of prescription drug for stroke patients: stroke survivors serving as patient partners on the study identified "home-time" or the number of days when a patient is living at home, not hospitalized or in another institution as an important new outcome. This input from patients was vital in directing the study toward an outcome that they truly cared about.
- Chronic pain study: The initial survey tool was lengthy and to be administered over the phone. Patient partners, feeling that a lengthy phone survey would create a barrier for chronic pain patients, shortened and redesigned the tool to be self-reported and -paced, facilitating greater ease of participation.

- Post-discharge care study: Clinicians have been actively involved in the analysis of initial data runs and have asked key questions that have helped refine the study's analytic plan. The study is now looking more closely at variations in patterns of care and outcomes.

2. **CONDUCTING THE STUDY:** Describe how patient and stakeholder partners will participate in the study conduct. (As you fill out Section 2 of your Engagement Plan, refer to the information below.)

Potential activities include:

- Drafting or revising study materials and protocols, to ensure feasibility for clinicians and patient participants.
- Participating in recruitment of study participants, to increase and sustain recruitment and ensure viability of the study.
- Participating in data collection and data analysis, to lend unique and varied perspectives on interpretation of the data.
- Participating in the evaluation of patient and stakeholder engagement, to ensure authenticity and value of engagement.
- Serving as a patient representative on a data safety monitoring board, to make the DSMB composition more robust and patient-centered.

Real-World Examples:

- Chronic pain study: The informed consent document is developed with patient partners to make it understandable to study participants. This involvement is anticipated to improve recruitment because potential participants will feel more informed and comfortable.
- Large pragmatic study about chronic pain; Patient partners will assess the patient-centeredness of the care delivered in the study by following (with their consent) the participant through all aspects of study. The observations of the patient partners will be used to improve study processes and make them more patient-centered.
- Asthma study: Clinicians and patients both provided guidance on who should deliver the intervention, when it should be provided during the process of care, and how it should be delivered. These suggestions are intended to make the study more streamlined into the usual provision of care for both patients and clinicians.
- Falls prevention study: A caregiver of aging parents who have experienced falls is serving as a patient/caregiver representative on the project's data safety monitoring board. A patient/caregiver representative serving in that capacity can offer interpretations of benefit, risk, and data analysis from a lived-experience perspective.
- Pediatric surgery study: Parent partners shared that, were they being approached to participate in the study, they'd feel more comfortable if the person discussing the risks and benefits of surgery (and involvement in the study) was a surgeon. When that adjustment was made to the protocol, rates of recruitment increased.

3. **DISSEMINATING THE STUDY RESULTS:** Describe how patient and stakeholder partners will be involved in plans to disseminate study findings and to ensure that findings are communicated in understandable, usable ways. (As you fill out Section 3 of your Engagement Plan, refer to the information below.)

Potential activities include:

- Identifying partner organizations for dissemination, to ensure meaningful and direct connections with end-users.
- Planning dissemination efforts, shaping study design and protocol from the very beginning to be focused on the final product.
- Participating in dissemination efforts, such as authoring manuscripts and presenting study findings, to offer the patient and stakeholder perspective and to reach new and different audiences
- Identifying opportunities to present or share information about the study, even as it is in progress, to move away from traditional models of dissemination and think more creatively about how to get information into the hands of those who need it.

Real-World Examples:

- Trauma study: The research team will convene a policy summit with relevant professional societies during the third year of the study to focus on identifying ways to speed the implementation of findings into practice.
- Care planning study: A national investing and financial planning firm is expanding their educational services to seniors, families, and their own financial planners. This firm will link to the study's website from its national website, and will disseminate the tool through their newsletters, financial planning conferences, and directly to high-impact planners.
- Large pragmatic study comparing surgery to antibiotics: Seven payers, three policymakers, and four large employers provided letters of support for the study and have agreed to disseminate findings to their networks when results are available. This involvement will ensure broad-based and diverse dissemination.
- Neurology study: The research team presented at a neurology patient advocacy conference to inform the community that this research was ongoing and to stay tuned for future results.
- Large pragmatic study about chronic pain: Physical therapists partnering in the study will design a Continuing Education (CE) program that will be delivered as part of the intervention. Patient partners will contribute by providing feedback on what kind of therapy and communication techniques will be more or less likely to be effective during an acute pain episode. Though also used during the course of the study, this CE can be an important dissemination tool upon study conclusion.