

Introduction to PCORI Applications

What is PCORI?

The Patient-Centered Outcomes Research Institute (PCORI) funds **comparative effectiveness research (CER)**. CER compares two or more screening tests, diagnostic tests, or interventions and compares risks and benefits of different approaches. What makes PCORI different as a funding agency is its commitment to:

- **Methodological standards** for conducting CER, and
- **Stakeholder engagement** (e.g., patients, families, providers, health systems, payers) in all phases of the research process, from development of a research question and study design to dissemination of findings. This means stakeholders must be involved developing the study question and design PRIOR to grant submission.

Before beginning an application to PCORI, we recommend investigators:

- Understand the overall mission of PCORI (www.pcori.org)
- Read their frequently asked questions (FAQs) (<http://www.pcori.org/funding-opportunities/funding-center/faqs-for-applicants/>)
- Read the PCORI Methodology Report (<http://www.pcori.org/research-we-support/the-pcori-methodology-report/>)
- Review PCORI's online applicant trainings that discuss the PCORI mission, application submission process (including how to access their online system, develop budget documents, stakeholder engagement plans, etc.), and review criteria (<http://www.pcori.org/funding-opportunities/funding-announcements/applicant-training/>).

Why This Worksheet?

This worksheet specifically focuses on the stakeholder engagement requirement of PCORI-funded research. It is designed to help researchers develop high quality PCORI proposals that meet patient and stakeholder engagement requirements in two sections of a PCORI proposal:

1. **The Patient and Family Engagement Template (3 pages)**. This section does not count toward specified page limits in the Research Proposal, and specifically asks about engagement of patient and family partners. Other stakeholders are not addressed in this template. The template is due with the proposal, not with the letter of intent (LOI), but it does not hurt to submit it along with the LOI. Merit reviewers use the template to answer specific questions they have about patient and family engagement. You can *use this template to index the sections of the research proposal where patient engagement activities are addressed*.
2. **The Engagement section of the Research Proposal (15 pages unless otherwise specified)**. While the template addresses only patient and family engagement, this section addresses engagement of patients and other stakeholders. Although it may seem redundant, *it is necessary to submit both the engagement template and engagement information in the Research Proposal*. The requirement to include this information in both places may change in future funding cycles, but it will remain in place until further notice.

In PCORI-funded research, patients represent a different kind of stakeholder. It is important to demonstrate a partnership with patients that predates the identification of a research topic and the development of a relevant research question. Other stakeholders may be identified, recruited, and engaged after a topic is identified and research question is developed.

This worksheet is organized into four sections:

- 1. A partnership with patients**
- 2. Topic identification and question development**
- 3. Identification and recruitment of other stakeholders**
- 4. Engagement plan**

Section 1. A Partnership with Patients

PCORI defines a patient as a (1) person who has lived with and/experienced an illness or injury, (2) a caregiver or family member of such a person, or (3) a member of a relevant advocacy organization.

To complete this section, we recommend answering the following questions:

1. Describe the patient population with whom you have an existing relationship. Include descriptions of all three types of patients in PCORI's definition.
2. How long have you been working with this patient population?
3. In what capacity have you been working with the patient population? Several options to answer this question may include:
 - I am a patient, family member or advocate [Note: All stakeholders, including researchers, can play multiple roles in PCOR research. PCORI recognizes and allows researchers to self-identify as patients; however, it is always recommended to identify some patients in your partnership that do not also represent other stakeholder communities].
 - I am a researcher who partners with patients, family member or advocates.
 - I am a research navigator who bridges patients and researchers.
4. Describe recent forums, activities and dates of importance in your partnership.

Section 2. Topic Identification and Question Development

To complete this section, answer the following questions:

1. What activities did you undertake jointly with patients to identify a research topic? These activities may include both a topic nomination and a prioritization process.
2. What criteria did your partnership use to establish topic priorities? Your response may include the following or other options:
 - Appropriateness
 - Magnitude
 - Severity
 - Feasibility of correcting
 - Replication
 - Duplication
 - Others
3. What procedures did you use to identify and refine research questions related to each priority topic?

Section 3. Identification and Recruitment of other Stakeholders

This section covers four steps:

- Step 1: Identify relevant stakeholder communities.**
- Step 2: Describe the rationale for including each stakeholder community.**
- Step 3: Determine a target number for each stakeholder community and sub-community.**
- Step 4: Identify the names of individuals and organizations.**

Step 1: Identify relevant stakeholder communities

Tip: To complete Step 1 and Question 1, scan the 7Ps Framework and consider whether all of the seven stakeholder communities make health care decisions that are relevant to your research question.

The 7Ps Framework

Category	Description
Patients and Public	Current and potential consumers of patient-centered health care and population focused public health, their caregivers, families and patient and consumer advocacy organizations.
Providers	Individuals (e.g. nurses, physicians, mental health counselors, pharmacists, and other providers of care and support services) and organizations (e.g. hospitals, clinics, community health centers, community based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations.
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care.
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care.
Policy Makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities.
Product Makers	Drug and device manufacturers
Principal Investigators	Other researchers and their funders

To complete this step, answer the following question:

1. Who are the decision-makers the research is intended to inform?

Step 2. Describe the rationale for including each stakeholder community

Tip: As you complete Steps 2 through 4 below, use the following table shell to carefully document the process and results. The table places the 7Ps stakeholder communities in the major rows and potentially relevant sub-communities in rows below them. The sub-communities in this table shell are presented for illustration purposes only; the sub-communities you identify and recruit may be different.

The 7Ps Identification and Recruitment Tool

Category	Subcategory	Rationale	Target Number	Name
Patients and the public				
	Patient, patient advocate			
	Community member, consumer			
Providers				
	Clinicians - specialist			
	Clinicians - primary care			
	Other provider - nursing, hospitals, etc			
Purchasers				
	Private employer			
Payers				
	Private insurers			
	Medicare (CMS)			
	Medicaid			
Policy Makers				
	FDA, CMS, HRSA, CDC or other			
	Specialty society or guideline developer			
Principal Investigators and Funders of Research				
	Clinical research			
	Health services / policy research			
Product Makers (Devices)				
	Drug Maker			
	Device Maker			
TOTAL				0

To complete this step, answer the following questions:

1. What decisions do these stakeholders (decision-makers) have to make?
2. How can research lead to informed decision-making for these stakeholders?
3. To elaborate further on your response to question 2, how can engagement with each of the stakeholders:
 - a. Improve the relevance of your research questions(s)?
 - b. Increase the transparency of your research activities?
 - c. Accelerate the adoption of evidence in stakeholder decision-making?

Step 3. Determine a target number for each stakeholder community and sub-community

To complete this step, answer the following questions:

1. Will multi-stakeholder voting or prioritization take place? If yes, how does the target number of each community establish a reasonable balance of perspectives?
2. In what kind of research-related activities will stakeholders engage?
3. How did the planned activities influence the target numbers for each stakeholder community and sub-community?
4. What additional considerations, if any, did you use to establish the target number for each stakeholder community and sub-community?
5. How does the target number for each community help you maintain a balance of perspectives?

Step 4. Identify the names of individuals and organizations

Effective stakeholders possess good communication skills. They can articulate their perspectives clearly and are able to hear other perspectives. In some fields, semi-professional stakeholders may be available to serve as patient or community representatives. The advantage of these individuals is that they understand the research process and often are prepared to be successful as stakeholders. At times, however, these individuals may be so professionalized that they are less effective at representing their constituency.

To identify people, you might use personal and professional networks, literature reviews, membership lists from previous panels, or consider taking a sample from a population of interest. Make the initial contact with potential stakeholders via email or phone. Record the response, acceptance and attrition rates.

To complete this step, answer the following questions:

1. What process did you use to identify organizations and individuals to represent each stakeholder community and sub-community? If you used different methods for different groups, specify. Your responses may be drawn from the following options, or they may include other processes.
 - Personal and professional networks
 - Literature reviews
 - Membership lists from previous panels
 - Random sample
2. Which of the proposed stakeholders, if any, are 'professionalized' representatives of their stakeholder community?
3. What evidence does the research team have that the proposed stakeholders can articulate their perspectives?
4. What evidence does the research team have that the proposed stakeholders can hear other perspectives?

Section 4. Engagement Modes and Methods

It is important to consider engaging with stakeholders *before* the research project begins, *during* the conduct of research activities, and *after* the research is concluded. Stakeholders can help before the research program begins by defining and prioritizing research topics and questions. They can help during the conduct of research by advising on technical issues related to patient recruitment and protections and by participating in research design and analysis decisions. They can help after the research is completed by supporting dissemination and implementation of findings.

This section covers five steps that will help you complete the process of identifying and recruiting other stakeholders:

- Step 1: Identify the level of engagement**
- Step 2: Identify the methods and modes of engagement**
- Step 3: Orient and train stakeholders**
- Step 4: Make engagement work**
- Step 5: Evaluate engagement**

Step 1: Identify the level of engagement

Once you have identified why your research project will engage stakeholders and who you will engage, you want to identify what level of engagement is appropriate for this group of stakeholders.

- *Advisor:* Stakeholders provide input and feedback, but are not necessarily involved in decision-making about the research process. You may use stakeholder advisory boards that meet periodically to provide consultation to a study.
- *Participant:* Stakeholders may participate in conducting research, including topic identification and question development, data collection and analysis, and dissemination and implementation of findings. You may hire patients and other stakeholders to perform discreet tasks in the research plan.
- *Partner:* Stakeholders are involved in making decisions about the research project; they may also be co-investigators of the research project. You may partner with patients in shared decision-making regarding the entire research process as in community-based participatory research (CBPR) or action research.

Tip: Be cognizant of the level of engagement the research staff are trained to manage. Higher levels of stakeholder engagement require openness toward changing the research plan as a result of stakeholder engagement.

To complete this step, respond the following questions or requirements:

1. What level of engagement is appropriate for this project?
2. Describe how research staff prepared with the right kind of expertise or training to engage at this level.
3. Will different stakeholder communities be engaged at different levels? If so, how?
4. Will the level of engagement change with the stage of the project? If so, how?
 - What is the planned level of engagement before the research begins, in the identification of the research topic and refinement of research question(s)?
 - What is the planned level of engagement during the conduct of research activities?
 - What is the planned level of engagement after the research activities are concluded, in the dissemination and implementation of findings?

Step 2: Identify the methods and modes of engagement

Stakeholders hold diverse opinions, come from different educational and cultural backgrounds, and use different idioms and language. It is important to consider how the methods and modes of engagement will work for different types of stakeholders. The methods of engagement may be described by different types of group and individual contact, such as meetings, interviews, surveys, and focus groups. The modes of engagement may include finer details such as contact via webinar, teleconference, in-person meetings, shared web space, email, and phone. It may be important to make special considerations for interaction with patients and the public, whose familiarity with research may not be fully formed. Additional preparation or separate meetings for patients and the public can help to improve their familiarity.

To complete this step, answer the following question:

1. What are the methods by which the research team will engage stakeholders of different types? Will you vary our methods over the course of the study? Your response may include some of the following, or other options:
 - Meetings
 - Interviews
 - Surveys
 - Focus groups

2. What are the modes by which the research team will engage stakeholders of different types? Your response may include some of the following, or other options:
 - Webinars
 - Teleconferences
 - In-person meetings
 - Shared web space
 - Email
 - Phone

3. What special considerations were give to engagement with patients?

Step 3: Orient and train stakeholders

All stakeholders need training and support to engage effectively in a research program. Orientation may include information on the proposed research and some background on the purpose of stakeholder engagement. Information about administrative issues such as financial support (reimbursement, honoraria, staffing, none) and practical support (administrative, travel, etc.) may be relevant. A clear delineation of roles and expectations is important. Stakeholders will often not know each other previously and will need to develop a shared set of rules (spoken or unspoken) for working together. Collect stakeholder disclosures and conflict of interest (COI) information.

Tip: Be mindful of power dynamics within any group. Some individuals may feel more comfortable expressing their opinions in a group and it is important to make sure all voices have the opportunity to be heard.

To complete this step, answer the following question:

1. What kind of training and support will be offered to stakeholders?
2. What information will be included in orientation? Your response may include some of the following, or other options:
 - The proposed research
 - The purpose of stakeholder engagement
 - Administrative issues such as financial support (reimbursement, honoraria, staffing, none) and practical support (administrative, travel, etc.) may be relevant.
 - Description of roles and expectations
3. How will the research team and stakeholders develop a shared set of rules for working together?
4. What is the process for collecting stakeholder disclosures and conflict of interest (COI) information?

Step 4: Make engagement work

Managing group processes requires a skilled facilitator who can create an environment where all stakeholders feel their opinion can be expressed and heard. A skilled facilitator helps groups meet specified outcomes *and* allows for unanticipated ideas to surface. Skilled facilitation also involves being able to manage debate, divergent opinions and conflict. Sometimes, group process is aided by interactive exercises that help to elicit stakeholder opinions. To support interaction and dialogue between stakeholders, it is useful to take notes and circulate them for comment. It is imperative that follow-up happen on action items discussed at meetings and that subsequent meetings report on the follow-up action. This helps stakeholders feel as though their opinions are valued.

Tip: Tufts CTSI's Community Engagement team developed a curriculum guide for working with community leader stakeholders. This guide has many useful tips for creative ways for engaging stakeholders:

<http://www.tuftsctsi.org/~media/Files/CTSI/Library%20Files/Building%20Your%20Capacity%20Curriculum%202012.ashx>

To complete this step, answer the following question:

1. What will the research team do to ensure a productive group process?

Step 5: Evaluate engagement

It is helpful to incorporate a process and an outcomes evaluation into your stakeholder engagement plan. Process evaluation gives all stakeholders an opportunity to comment on what is working well with the group and what needs to be changed or improved. Process evaluation can happen after every meeting or during the research process. Outcome evaluation gives the research team and funders information on how effective engagement was at improving the research. Three key dimensions of research improvement are the impact on the relevance of research questions, the transparency of research activities, and the adoption of research findings. It is imperative the evaluation findings be acted upon.

To complete this step, answer the following question:

1. How will the research team evaluate the process of engagement?
2. How will the research team evaluate the outcomes of engagement? Your response may include detail on how you will gather information on the following outcome dimensions, or other dimensions.
 - Impact on the relevance of research questions
 - Impact on the transparency of research activities
 - Impact on the adoption of research findings
3. What are the plans for acting on findings of both the process and outcome evaluations?