

Establish a clear purpose for your stakeholder engagement activities.

After you have **Identified Where Your Research Question Falls on the Tufts CTSI CER Spectrum** you might answer the following questions to establish a purpose for your activities. Your answers to these questions may be helpful in developing written orientation materials that you can use when it comes time to orient and train stakeholders about your project.

- a. **Who are the decision-makers the research is intended to inform?**
- b. **What decisions do these stakeholders (decision-makers) have to make?**
- c. **How can research lead to informed decision-making for these stakeholders?**
- d. **How can engagement with each of the stakeholders:**
 - i. **improve the relevance of your research questions(s)?**
 - ii. **increase the transparency of your research activities?**
 - iii. **accelerate the adoption of evidence in stakeholder decision-making?**

Examples of stakeholder engagement have ranged from having a **stakeholder advisory board** that meets periodically to providing consultation to a study, to shared decision-making regarding the entire research process (as in **community-based participatory research (CBPR)** or **action research**).

Plan the identification and recruitment of stakeholders.

As you plan and conduct the recruitment phase of this process, remember to carefully document your recruitment methods and outcomes.

Step 1

Scan the 7Ps Framework and discuss whether all 7Ps are relevant.

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.
Policymakers	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

Step 2

Turning to the 7Ps Identification and Recruitment Tool (next page), describe the *rationale* for including each stakeholder type. Identify relevant subcategories of stakeholders. Several examples of stakeholder subcategories are included in the 7Ps Tool, for illustration purposes.

Step 3

Determine the *target number* for each stakeholder type that you will need. Several considerations are important in this step. Federal funding may require compliance with the Paperwork Reduction Act, limiting the total size of a stakeholder panel or advisory board to 10 or fewer non-Federal participants. It is important to determine up front whether voting or prioritization will take place, in which case you will need to establish a balance of competing perspectives.

Step 4

Identify the *names* of individuals and organizations who can represent each stakeholder type, until you fill the panel. To identify names, you might use personal and professional networks, literature reviews, membership lists from previous panels, or even 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.

The 7Ps Identification and Recruitment Tool				
Category	Subcategory	Rationale	Target Number	Name
Patients and 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			
Policymakers				
	FDA, CMS, HRSA, CDC, other			
	Specialty society or guideline developer			
Product Makers				
	Drug Maker			
	Device Maker			
Principal Investigators				
	Clinical research			
	Health services / policy research			
	TOTAL			

Planning and Implementing the Engagement of Stakeholders

Step 1 Stakeholder orientation and training. 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) 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.

Step 2 Engagement Modes and Methods. 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 webinars, teleconferences, 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. In some fields, semi-professional stakeholders may be available to serve as patient or community representatives. The advantage of engaging these individuals is 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

Step 3 Engagement Activities. Exactly what you ask your stakeholders to do will depend in large part on **Where Your Research Question Falls on the Tufts CTSI CER Spectrum**. It is important in every case to consider engaging with stakeholders *before* the research project begins, *during* the conduct of research activities, and *after* the research is concluded. For example, stakeholders can help before the research program begins by defining and prioritizing research topics and questions. They can help while research is conducted 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.

Step 4 Making Engagement Work. It is important to identify stakeholders with good communication skills, people who can articulate their perspectives clearly and can listen to and hear other perspectives. To support interaction and dialogue between stakeholders, you may want to take notes at stakeholder meetings and circulate them for comment.

*Adapted from Concannon et al, A new taxonomy for stakeholder engagement in patient-centered outcomes research. *Journal of General Internal Medicine*, 2012.