Tufts UNIVERSITY | Graduate School of Biomedical Sciences

Course Syllabus

Health Care Activism, Community Health, and Patient-Centered Research

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Course Information:
Credit/s: To be determined by the Registrar based on class contact hours
Grading Option: TBD
Required or Elective:
CTS-0549 Credit/s: 1 credit, 15 contact hours
PHPD-NNN Credit: 0.5 credit, 21 contact hours
Prerequisites: None

Course Contact Hours, Meeting Schedule, and Location

- PHPD degree students will participate in eight class meetings from Tuesday, March 8 through Tuesday, May 8; location TBD
- CTS degree students will participate in six class meetings from Tuesday, March 8 through Tuesday, April 19; two additional meetings on April 26 and May 3 are optional; location TBD

*Class will not meet on Tuesday March 22, 2021

Brief Course Description

This introductory course covers three approaches to stakeholder and community engagement in health-related research. We refer to these approaches as traditions, since each draws from one or more distinct academic discipline(s) and was developed in its own era of civic reform.

- *Patient-centered research* in which researchers initiate engagement members of the public in research work to make biomedical research more useful
- *Community-based health research* in which researchers and communities partner to co-create research that can address community needs
- *Health care activism* in which members of the public organize to influence publicly-funded research.

Learning Objectives

At the conclusion of the course students should be able to:

1. Compare and contrast the historical framework, methodology, and known impacts of three distinct approaches to involving the public in research: researcher-, partnership-, and public-initiated engagement.
2. Use principles and insights from the latest "tradition" -- researcher-initiated engagement – to advise a peer on their stakeholder identification plan.
3. Use principles and insights from the latest "tradition" -- researcher-initiated engagement – to develop your own research engagement plan
4. Identify potential impacts of stakeholder engagement in your own research.

Course Texts and Materials:

Articles from the literature are posted to the course website. Please note that all reading assignments are grouped within the first three lectures of the course.

Assignments and Grading:

The course is structured to assess whether your written work represents a command of course content.

ASSIGNMENTS	GRADING WEIGHT
Class Participation	10%
Assignment 1 Policy Memo (Objective 1)	15%
Assignment 2 Peer Review Memo (Objectives 1 and 3)	25%
Assignment 3 Stakeholder engagement plan (Objective 2, 3, and 4)	50%
Total:	100%

Student evaluations will be based on the following milestones and assignments. Please write your name and the date of submission at the top of each written assignment.

Class Participation

Class participation will be evaluated on the basis of your active contributions to class discussions throughout the course and by timely submission of Worksheets 1-3 (see course schedule, below).

Policy Memo

You will be asked to respond in a policy memo to one of three case studies (you will choose one). The memo should be addressed to your research advisor or the chair of your research department, and it should summarize your recommendation(s) on how to respond to an unexpected situation that could affect the course of your research or of the department's research portfolio. Assume that your advisor or chair will have 5 minutes to read the memo, so get right to the point while giving enough context to support your recommendation(s). At the following link is a resource on writing policy memos: http://libguides.usc.edu/writingguide/policymemo.

Each case study is drawn from the real-life experiences of researchers working to advance evidence in clinical medicine, health services, or health policy. Case study 1 is about an unanticipated new public policy that may halt your work. Case study 2 is about a citizen movement that could seriously slow down your progress. Case study 3 presents an unexpected opportunity for new partnered research. Following are brief descriptions of each case study. Longer versions are included the syllabus appendix.

Case Study #1: Science Policy, 2010

In August 2010 a District Court ruling in Washington, DC freezes Federal funding for human embryonic stem cell research. This funding freeze stops grant funding to your lab. You learn of this when a *Boston Globe* reporter calls for comment—prior to this call you were completely unaware of the simmering controversies surrounding embryonic stem cell research.

Case Study #2: Patient Activism, 1992

People living with breast cancer and breast cancer advocacy groups petition the courts to gain access to high density chemotherapy with autologous bone marrow transplant (HDC-ABMT), a surgical intervention that is currently the subject of intensive patient recruitment for study in NIH-funded trials. Patient advocacy groups win in the courts and payers begin to cover this therapy without conclusive evidence for its efficacy. Your trial enrollments suddenly plummet as patients no longer need the trial to gain access to this intervention.

Case Study #3: A Community and Academic Partnership, 2019

At CTSI's Translational Research Day, a community leader in Boston's Chinatown indicates that gambling addiction is a prevalent but silent problem in the community. The community leader reports serious concern about this problem, in particular because of a new casino being built in a nearby community. You learn from community members that local funding is available to address community-driven research on gambling addiction. You decide to approach community members to begin a discussion on this topic.

Peer Review Memo

Write a memo reviewing a peer's drafts of Worksheets 1 and 2. Please remember that the most useful peer reviews recommend specific changes or corrections that can strengthen a proposal. Suggesting a fix is more helpful and less hackle-raising than writing a paragraph about what's wrong.

Suggested format

a. Record the study title, your peer's name, and your name in the memo header.
b. Address the memo to your peer, not to the course instructor.
c. Summary comments. In 5-10 lines, summarize the engagement plan's principal strengths and weaknesses. Recommend changes that could strengthen the proposal.
d. Detailed comments. Evaluate the following worksheet sections
    - Rationale for engagement
    - Relevant stakeholder communities
    - Roles for each stakeholder community over the course of preparing for, carrying out, and using the research.
    - The engagement plan

Stakeholder Engagement Plan: Your major assignment is to gain practical understanding of your own potential stakeholder and community engagement plan for a thesis proposal, thesis, grant or current research project. Your final product should be a 500-word synopsis of your plan as developed in Worksheets 1-3 (submission of the worksheets along with the synopsis is optional but encouraged as they may help the instructor evaluate your plan). The 500-word synopsis should be written in the format you might use in a thesis or funding proposal. This synopsis is meant to be a practical and useful outcome of the course. It should include:

a. A description of stakeholder communities that will be engaged. This may include a very brief summary of why these stakeholders are relevant to your research. It may also describe a plan for recruiting individuals to represent each of the stakeholder communities you wish to involve.
b. A plan describing the research activities that stakeholders will be involved in. It should also describe how they will be engaged in the work.

A plan to assess the impact of your engagement plan on 1) your research budget and productivity, 2) research procedures, and 3) research outcomes.

Penalties for late or incomplete assignments:

Late assignments will not be accepted without advance permission of the course instructor.

Course and Assignment Schedule:

DATE	LOCATION	TOPIC OR CLASS TITLE	ASSIGNMENTS & ACTIVITIES	LECTURER(S)
1 March 8	online	**Introduction**	Pre-course survey: research interests and goals	Concannon
2 March 15	online	**Tradition III – Patient-centered research**		Concannon
3 March 29	online	**Tradition II – Community Health Partnerships**		Palm, Sege
4 April 5	online	**Tradition I – Patient and Public Activism**		TBD
5 April 12	online	**Identifying and recruiting stakeholders**	Assignment 1 Policy Memo: respond to a case study of your choice Draft Worksheet 1: timely submission counts toward class participation	Concannon
6 April 19	online	**Planning and evaluating engagement activities**	Assignment 2 Peer Review Memo: review a peer's Worksheet 1 Draft Worksheet 2	Concannon
7 April 26	online	**Design studio I**	Draft Worksheet 3	Concannon, Palm
8 May 3	online	**Design studio II**	Assignment 3 Stakeholder Engagement Plan: 500-word synthesis of your Final Worksheets and optionally, Final Worksheets 1-3	Concannon, Palm

NOTES: *This schedule is subject to modifications at the discretion of the course director. Required submissions are in bolded text. Optional submissions are in regular text.*

Lectures, Readings, Guest Presentations, and Handouts

1. Introduction to the course

In this course, we teach about *three academic traditions* of engagement between researchers and members of the public. These three traditions originated and were developed and studied in distinct academic disciplines. The traditions are reflected in the course title:

- **Tradition I: Health Care Activism**, in which patients and the public initiate engagement – often uninvited and sometimes hostile – to address failures of the health system. How activism and movements work, and how professionals can respond effectively, has been studied extensively over a century and more in the disciplines of political science and sociology.
- **Tradition II: Community Health Partnerships**, in which researchers and community representatives form partnerships to address health needs that are a priority of the community. How to form, participate in and assess community partnerships has been studied for at least the last 60 years in the disciplines of education, labor, and public health.
- **Tradition III: Patient-Centered Research**, in which researchers initiate engagement with patients, clinicians, hospital leaders, industry, insurers, policy makers, and others in order to make research more relevant, transparent, and useful. How to identify relevant stakeholders, plan effective engagements with stakeholders, and evaluate the impacts of engagement on research has been studied for at least 20 years in the disciplines of clinical, health services, and health policy research.

We present these three traditions in reverse order over lectures 2-4 because most of you are researchers who have come to learn about the practical steps of initiating engagement with stakeholders or about forming effective community partnerships.

The readings for this first lecture present one example from each of the traditions. These are inspiring stories of success from each of the traditions. Please enjoy reading them prior to this first lecture. We will return to each example in subsequent lectures.

Readings

- **Tradition I Example:** Epstein, S. (1995). The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials. *Science, Technology, & Human Values, 20*(4), 408-437. Retrieved March 6, 2021, from http://www.jstor.org/stable/689868
- **Tradition II Example**: Sprague Martinez L, Reisner E, Campbell M, Brugge D. Participatory Democracy, Community Organizing and the Community Assessment of Freeway Exposure and Health (CAFEH) Partnership. *Int J Environ Res Public Health*. 2017;14(2):149. Published 2017 Feb 4. doi:10.3390/ijerph14020149
- **Tradition III Example:** Xian Y, O'Brien EC, Fonarow GC, Olson DM, Schwamm LH, Bhatt DL, Smith EE, Suter RE, Hannah D, Lindholm B, Maisch L, Greiner MA, Lytle BL, Pencina MJ, Peterson ED Real world effectiveness of warfarin among ischemic stroke patients with atrial fibrillation: observational analysis from Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER) study. *BMJ* 2015; 351

Handouts (included as attachments in the syllabus)

- Policy Memo Case Studies 1-3
- Worksheets 1-3

2. **Tradition III – Researcher-initiated engagement**

Readings

- Forsythe LF, Heckert A, Margolis, MK, Schrandt S, Frank L. Methods and impact of engagement in research, from theory to practice and back again: early findings from the Patient-Centered Outcomes Research Institute. Qual Life Res (2018) 27:17–31.
- Concannon TW, Grant S, Welch V, Petkovic J, Selby J, Crowe S, Synnot A, Greer-Smith R, Mayo-Wilson E, Tambor E, Tugwell P. Practical guidance for involving stakeholders in health research. *J Gen Int Med,* 2019 Mar.

3. **Tradition II – Partnership-initiated engagement**

Readings

- Chang C, Salvatore AL, Lee PT, San Liu S, Tom AT, Morales A, Baker R, Minkler M. Adapting to Context in Community-Based Participatory Research: ''Participatory Starting Points'' in a Chinese Immigrant Worker Community. *Am J Community Psychol* (2013) 51:480–49.
- Israel BA, Schulz AJ, Parker EA, Becker AB. Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health. *Ann Rev Public Health*. (1998) 19:173–202.
- Ortiz K, Nash J, Shea L, Oetzel J, Garoutte J, Sanchez-Youngman S, Wallerstein N. Partnerships, Processes, and Outcomes: A Health Equity–Focused Scoping Meta-Review of Community-Engaged Scholarship, Annual Review of Public Health 2020 41:1, 177-199

4. **Tradition I – Patient- and Public-initiated engagement**

Readings

- Putnam, Robert D. "(1995a). Bowling alone: America's declining social capital. Journal of Democracy, 6, 65-78." (1995).
- Jean L. Cohen, "American Civil Society Talk," in Robert K. Fullinwider, ed., *Civil Society, Democracy, and Civic Renewal*, pp. 55-85
- Tilly, Charles, and Lesley J. Wood. *Social Movements 1768-2012*. Routledge, 2015, pp. 1-15

5. **Identifying and recruiting stakeholders**

There are no required readings for this lecture

A guest lecturer will present an example of stakeholder engagement in their research

6. **Planning and evaluating engagement activities**

There are no required readings for this lecture

A guest lecturer will present an example of stakeholder engagement in their research

7. **Design Studio I -** attendance is optional for CTS students but required for PHPD students. Assignments (in bold, below) are due for all students.

   There are no required readings for this lecture

   A selection of students will present on their stakeholder engagement plans

8. **Design Studio II -** attendance is optional for CTS students but required for PHPD students. Assignments (in bold, below) are due for all students.

   There are no required readings for this lecture

   A selection of students will present on their stakeholder engagement plans

Diversity Statement

It is our commitment that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed, and that the diversity that students bring to this class be viewed as a resource, strength and benefit. It is our intent to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Please let us know ways to improve the course for you personally or for other students or student groups.

Modified from: University of Iowa College of Education

Religious Accommodations

Both university policy and Massachusetts law provide that students unable to attend classes, participate in required course or lab activities, or take a scheduled examination because of religious observance will be provided with reasonable opportunity to make up the course work without adverse effects. The University's Religious Accommodations Policy is available at https://oeo.tufts.edu/wp-content/uploads/ReligiousAccommodationPolicy.pdf. Students requiring an accommodation should contact the course director prior to the requested dates to work out suitable accommodations.

Important University Policies:

- ***Sexual Misconduct Policy:*** Tufts is committed to providing an education and work environment that is free from sexual misconduct. If you or someone you know has been harassed or assaulted, please contact Dan Volchok, the GSBS Sexual Misconduct Reporting Liaison, at 6-6767 or daniel.volchok@tufts.edu. He can help you find appropriate resources and discuss your options. Anonymous reporting is available through the Tufts anonymous Incident Report Form: (https://tuftsuniversity.ethicspointvp.com/custom/tuftsuniversity/oeo/form_data.asp).

Students may also obtain free confidential counseling through Talk One2One at 1-800-756-3124. Campus police may be contacted at 6-6911.

- ***Americans with Disabilities Act Policy:*** Tufts University is committed to providing reasonable accommodations for qualified individuals with disabilities. If you are interested in seeking accommodations in courses or in a laboratory setting, please contact Dan Volchok, the GSBS Disability Officer, at 6-6767 or at daniel.volchok@tufts.edu.

- ***Tufts Information Stewardship Policy*** outlines the actions all members of the Tufts community are expected to follow when working with institutional data and systems (https://it.tufts.edu/ispol).

- ***Academic Conduct:*** All students are responsible for compliance with all academic standards and policies, including plagiarism and academic integrity, as outlined in the Graduate School of Biomedical Sciences Student Handbook (https://gsbs.tufts.edu/studentLife/StudentHandbook).

- ***Disclosing Conflicts of Interest***: The course director and lecturers, including guest lecturers, are expected to disclose any significant financial interests or conflicts of interest that might undermine, appear to undermine, or have the potential to undermine the objectivity of their lecture content and assigned reading materials.

Attachments

Case Studies 1-3

Worksheets I-III

Case Studies 1-3

Case Study #1: Science Policy, 2010

You are a stem cell researcher who has been working for many years to discover new ways to use stem cells from human embryos to heal non-healing wounds in diabetic patients. You recently secured a 1.5-million-dollar, multi-year R01 grant from NIH to study how stem cells derived from human embryos could activate wound healing in ways that were not possible before. This line of research had become possible thanks to the Obama Administration's Executive Order of 2009, which provided opportunities to use new and potentially important embryo-derived stem cells for his research. The Executive Order reversed restrictive rules for use of human embryo-derived stem cells that had been in place for the previous 8 years of the Bush Administration.

However, in August 2010 a District Court in Washington, DC. ruled that the Obama Executive Order was not legal and froze all Federal funding on human embryonic stem cell research. This funding freeze stopped grant funding to your lab. You learn of this when a Boston Globe reporter calls you for comment—prior to this call you were completely unaware of the simmering controversies surrounding embryonic stem cell research.

Clearly, you had not been thinking much about the interaction of your research and the political, legal, and ethical questions being addressed by others. You now have to puzzle through the question of how to respond.

Your assignment is to address the following questions:

1. Can you modify your research to continue with stem cell work in some way?
    - Since these funding limitations were only for federally-funded research, might you turn to private sources of funds to continue this research?
    - Can you pause some work and keep other parts going while waiting for this policy to change?
2. Should you redirect your lab's work toward a different subject matter?
3. Is there some other step you can take?

To assist you in answering these questions, you might consider

- What personal and professional considerations are a factor in these decisions?
- Do any of these options pose risks or create potential benefits to…
    - your career or lab?
    - individuals or to communities?
- Which individuals and communities are important in your work going forward?
- How might you consider working with individuals and communities who use or are affected by this line of research?
- What benefits to your research might come from involving these individuals and communities?

Case Study #2: Patient Activism, 1992

You are a Co-Investigator on a clinical trial to study high density chemotherapy with autologous bone marrow transplant (HDC-ABMT), an intervention that holds promise in the treatment of breast cancer, but for which the efficacy in treating breast cancer is not established. You are currently managing intensive patient recruitment for your trial.

You are not aware that people living with breast cancer and patient advocacy groups have recently petitioned the courts to force health plans to pay for the procedure. Patient advocacy groups win in the courts and payers begin to cover this therapy without conclusive evidence for its efficacy. Your trial enrollments suddenly plummet as patients no longer need the enrollment to gain access to the intervention.

This takes you by surprise. What seems like a win for patients in the near term is a disaster for your first major clinical trial, and worse, it may substantially delay the development of evidence for or against this procedure.

Your assignment is to address the following questions:

1. How will you make the case to patients to enroll in your trial?
2. What aspects of the trial design might be altered to establish useful evidence?
3. Is there some other step you can take?

To assist you in answering these questions, you might consider

- How did you miss signals that this problem was brewing, and what could you have done to anticipate it and avoid impact on your trial?
- Now that most patients can get access to the procedure through insurance, what direct benefits do they receive by enrolling in your trial?
- Which individuals and communities are important in your work going forward?
- How might you consider working with individuals and communities who use or are affected by this line of research?
- What benefits to your research might come from involving these individuals and communities?

Case Study #3: A Community and Academic Partnership, 2019

You are new physician at Tufts Medical Center interested in addiction research. In the past, your work has focused on substance abuse. You attend CTSI's 2018 Translational Research Day, which is focused on addiction, where a community leader in Boston's Chinatown indicates that gambling addiction is a prevalent but silent problem in the community. The community leader reports serious concern in the community about this problem, and in particular because of a new casino being built in a nearby community.

During an afternoon community panel on this topic, you hear that gambling is related to immigration and poverty. Some gamble to relieve stress, as a form of entertainment, or to earn extra money. You also learn that, like other addictions, it can have negative impacts on family life. It can lead to spousal abuse, financial ruin, and neglect of children. Stigma is a persistent barrier to addressing the problem. You also learn that there are few places where people with a gambling disorder can be treated. There are a lack of clinicians out there who are skilled in treating people with a gambling disorder. At this panel, you are most surprised to learn that casinos target the Chinese community (among others) with chartered buses from Chinatown directly to Foxwoods.

The community panel also reveals that funding is available from the Massachusetts Gaming Commission to address community-driven research on gambling addiction. The panel indicates they are seeking partnership with a researcher who can help evaluate community-based solutions to address problem gambling. The community is particularly interested in finding someone who has an interest in Asian health equity. Over the course of the day, you have become intrigued by this research problem, and wonder if you are the right fit to partner with the community to address this problem. You decide to approach the community members to begin a discussion with them.

Discussion Questions:

1. What assumptions do you hold about the Chinatown community, gambling addiction, and the Tufts-Chinatown relationship?
2. How do social determinants of health influence the context of problem gambling?
3. How will identify people, organizations, and assets in the Chinatown community that can be part of planning a research program?
4. How will you work with the community to develop a research proposal to the Massachusetts Gaming Commission?
5. In a research project on this topic, which stakeholders are relevant?
6. What kind of training would be necessary for the research team and stakeholders?
7. How would you work with the community in research on this topic?

Worksheets 1-3

Worksheet 1. Identifying Stakeholders

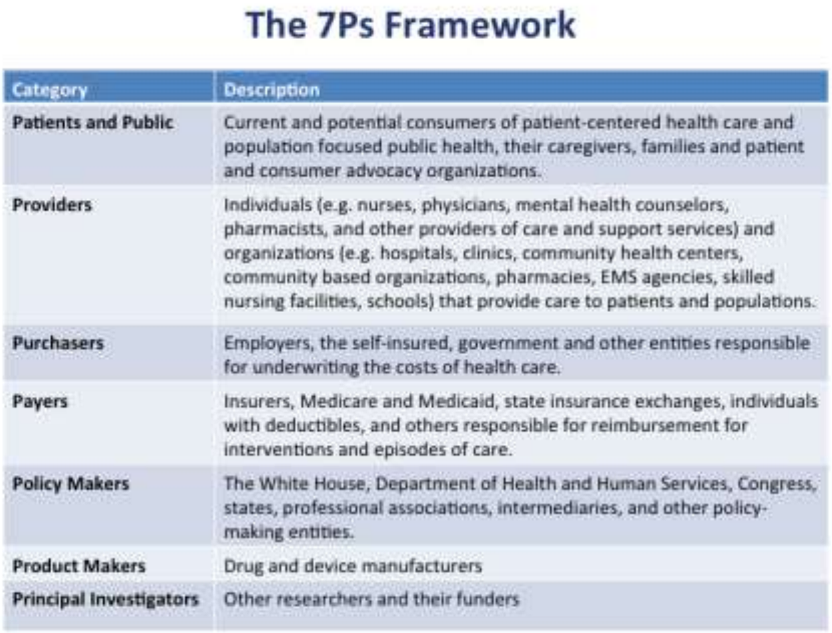
This worksheet comprises four steps:

- **Step 1: Identify relevant stakeholder communities**
- **Step 2: Determine a target recruitment number from each stakeholder community**
- **Step 3: Identify the names of individuals and organizations**

Step 1: Identify relevant stakeholder communities

To complete Step 1, scan the 7Ps Framework and consider whether all of the seven stakeholder communities make health care decisions that your research is meant to inform.

Use the table shell on page 4 to document the results.



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

1. Describe the health-related decisions that your research is meant to inform:

a. Which stakeholder group(s) makes these decisions? Specify both the major stakeholder categories and the specific “personae” within the major categories.

Definitions:
Major category, any of the 7PS,
Minor category: any subgroups you identify within any P,
Persona(e): the specific type of person or people you want to recruit within a major and minor category.

- Example 1a: for the major category Providers and minor category Pediatric Rheumatologists, one persona might be an early career Pediatric Rheumatologist working in a rural setting.
- Example 1b: for the major category Providers and minor category Pediatric Rheumatologists, another persona might be a clinician working with underserved populations within an urban teaching hospital.
- Example 2a: for the Major category Payers and minor category commercial insurers, one persona might be an economist working within a Health Economics Outcomes Research group within an insurance organization serving populations in the Midwest.
- Example 2b: for the Major category Payers and minor category commercial insurers, another persona might be a clinician working within a Quality Measurement unit in the Pacific Northwest.

b. Which stakeholder group(s) are affected by these decisions? Specify both the major stakeholder categories and the specific “personae” within the major categories.

2. How can research lead to informed decision-making for these stakeholders?

3. Describe some of the intrinsic goods you might expect to gain from engaging with these stakeholder groups:

   Specifically, how might engagement:

   a. Affect relationships between researchers and decision makers?

b. Affect the self-efficacy of some of the stakeholder communities?

4. Describe some of the instrumental goods you might expect to gain from engaging with these stakeholders:

Specifically, will engagement:

c. Improve the relevance of your research questions(s)?

d. Increase the transparency of your research activities?

e. Accelerate the adoption of evidence in stakeholder decision-making?

Step 2. Determine a target number for each stakeholder community and sub-community

Use the table shell on page 4 to document the results.

1. Do you have an engagement budget?

2. What is the total number of stakeholder representatives you can realistically afford to engage, and how?

3. Should some stakeholder communities have more representation in the project than others?

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 and power?

Stakeholder Community	Rationale for Involvement		Target #	Name
	Decisions they make	How they are affected		
Patients				
Providers				
Payers				
Purchasers				
Policy makers				
Product makers				
Principal Investigators				

Step 3. 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 working with professionals is that they may be better 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 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 e-mail or phone. Record the response, acceptance and attrition rates.

<u>To complete this step, answer the following questions:</u>

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.

2. Which of the proposed stakeholders, if any, are 'professionalized' representatives of their stakeholder community?

3. Do you have any concerns that some of the proposed individuals may need training or additional support to be effective participants in the work?

4. Do you have any concerns that some of the proposed individuals may not be successful in working on a large research team?

Worksheet 2. Planning Engagement Activities

This worksheet takes you through four steps. At the conclusion of this worksheet, consider writing a one paragraph summary of your responses. This summary may suffice to address the engagement requirements of a variety of funders.

Step 1: Summarize your rationales for engaging with stakeholders (from Worksheet 1)

Step 2: Describe the stakeholders with whom you will work (from Worksheet 1)

Step 3: Making research patient-centered

Step 4: How will stakeholders be involved?

Step 1: Summarize your rationales for engaging with stakeholders (from Worksheet 1)

Pre-specifying the rationale – or desired outcomes – of engagement is a critical factor in developing an engagement plan. By establishing the desired outcomes in advance, the study team can later evaluate the extent to which expectations have been met. This section points at ways to characterize the expected value of stakeholder engagement.

To articulate the rationale for engagement, the team might consider both its intrinsic and instrumental goods.

- Intrinsic reasons suggest that engagement is an end in itself. In other words, involving stakeholders may simply be the right thing to do, especially if public dollars are used. The principles of engagement call researchers and stakeholders to pursue intrinsic goods like autonomy, dignity, equity, inclusiveness, partnership, and participation; in contrast, superficial involvement can be insulting to stakeholders.
- Instrumental reasons suggest that engagement produces some other good worth having. For instance, involving stakeholders may make study questions more relevant, methods and approaches more transparent, findings more useful, and evidence more likely to be used in practice. If researchers wish our work to have detectable impact on health-related decisions, we should involve decision makers as we carry the work out.

1. In a few sentences, summarize the intrinsic and instrumental reasons you have set forth for engaging with stakeholders in your research agenda or program:

Step 2: Describe the stakeholders with whom you will work (from Worksheet I)

Previous frameworks have sought to help researchers identify stakeholders in their work. Concannon *et al* identified seven types of stakeholders in the Tufts-RAND 7Ps taxonomy for engagement; Deverka *et al* identified eight types in the Center for Medical Technology Policy framework for engagement; PCORI identified nine types in its engagement "rubric". Cochrane identified four audiences in its recent knowledge translation strategy. Tugwell *et al* named six types in a WHO Bulletin on knowledge translation for systematic reviews. By putting the first three of these models in a single table (see next page), it is possible to see that differences in the *number of* stakeholder types are largely a matter of classification, not a disagreement about who should be included. At least two of the approaches were developed and published simultaneously, suggesting independent agreement about which stakeholders are key to improving health research.

Each of these frameworks recognizes that identifying the right individuals to represent stakeholder perspectives is a challenge, as stakeholders within a single group may hold different views. Choosing a multi-stakeholder approach is even more complex given the need to consider how to assure that under-represented voices are heard, to ensure that the financial or academic interests of one group don't dominate the discussion, to manage group interactions and potential power imbalances, and to synthesize the views of different groups. It is important to be transparent about who was involved and why.

To complete this section, answer the following questions:

1. What model will you use to identify stakeholders?
2. What is the research for?
    a. Which communities make decisions the research is meant to inform?
    b. Which communities are affected by decisions the research is meant to inform?
3. What factors did you use to determine the size and composition of your stakeholder group(s)?
4. Summarize your stakeholder identification strategy in a few sentences.

7Ps Model[1]		PCORI Model[2]		CMPT Model[3]	
Type	**Description**	**Type**	**Description**	**Type**	**Description**
Patients and the Public	Current and potential consumers of patient-centered health care and population-focused public health, their caregivers, families and patient and consumer advocacy organizations.	Patients	Persons with current or past experience of illness or injury, family members or other unpaid caregivers of patients, or members of advocacy organizations that represent patients or caregivers	Patients and Consumers	Persons or organizations that represent the patient or consumer perspective generally, or within specific disease states, such as individuals with particular conditions, caregivers, patient advocates and 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.	Clinicians	Providers of health care in a clinical setting, including physicians, nurses, physician assistants, rehabilitative professionals, pharmacists, mental healthcare providers, complementary and alternative healthcare providers, and professional societies serving clinicians	Clinicians	Individuals who provide healthcare services, such as physicians, nurses, pharmacists, nurse practitioners, physician assistants and mental health providers
		Hospitals and Health Systems	Organizations where care is delivered, including public and private hospitals and health systems, urgent care centers, retail health clinics, and community health centers, and organizations representing these facilities	Healthcare providers	Institutions that deliver healthcare services, such as hospitals, nursing homes, outpatient clinics, clinical laboratories and accountable healthcare organizations
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care.	Payers	Those who function as financial intermediaries in the health system, including private insurers and public insurers, and organizations representing insurers, such as America's Health Insurance Plans	Payers and purchasers	Organizations that pay for healthcare goods and services, such as public and private insurers, health plans and employers
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care.	Purchasers	Those who purchase health benefits for employees and their dependents, including individual businesses as well as local, state, regional, and national business groups, coalitions that represent businesses, and health coalitions		
Product Makers	Drug and device manufacturers	Industry	Companies that design, invest in, or manufacture diagnostics, devices, pharmaceuticals, electronic records systems, and mobile apps, and organizations representing the life sciences industry, such as the Advanced Medical Technologies Association	Life sciences industry	Entities that develop and market medical technologies, such as pharmaceutical, medical device, diagnostic, biotechnology companies and organizations that represent life science company interests
Policy Makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities.	Policy Makers	Those who help craft public policy at any level of government, including federal, state, and local government officials; federal, state, and local units of government; and organizations that represent policy makers	Policy-makers and regulators	Individuals and organizations that create, monitor and oversee policies or regulations of healthcare-related issues, such as federal, state and local government agencies, medical and professional organizations and clinical guideline developers
Groups described in PCORI's definition of Training institutions are distributed in 3Ps: Principal Investigators, Providers and Policy Makers		Training Institutions	Those that deliver health professional education include public and private universities and colleges, individuals affiliated with the delivery or administration of health professional education, and trade or professional associations representing these institutions, organizations, and individuals	Groups described in PCORI's definition of Training Institutions are distributed in 3 CMTP types: researchers, policy makers and regulators, and healthcare providers	
Principal Investigators	Other researchers and their funders	Researchers	Those who conduct clinical research, including investigators or funders of research and organizations or associations representing the research community	Researchers	Individuals and their related organizations that develop scientific and clinical evidence, such as clinical researchers, health services researchers, social scientists and basic scientists
				Research Funders	Entities that provide monetary support for research efforts, such as government, foundations and for-profit organizations

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[1] Concannon TW, Meissner P, Grunbaum JA, McElwee N, Guise JM, Santa J, Conway PH, Daudelin D, Morrato EH, Leslie LK. A new taxonomy for stakeholder engagement in patient centered outcomes research. Journal of General Internal Medicine, 2012 Aug; 27 (8):985-991. PMCID: PMC3403141.

[2] PCORI's Stakeholders, http://www.pcori.org/funding-opportunities/what-we-mean-engagement/pcoris-stakeholders. Accessed February 2017.

[3] Deverka PA, Lavallee D, Desai PJ, Tunis SR. Journal of Comparative Effectiveness Research, 2012 Mar; 1(2):181-194.

Step 3: Develop a long-term, sustained relationship with patients and the public

Step 3 is especially important for applicants for PCORI funding or other funders who support patient-centered research. If your research is not meant to be patient centered, you may skip this section.

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.

<u>Describe patients and your history working with patients:</u>

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 an 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.

<u>Work with patients on topic identification and question refinement</u>

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?

<u>Describe how the research qualifies as patient-centered</u>

1. How is the study population and setting representative of the patients and communities affected by the condition of study?

2. How is the research focused on outcomes of interest to patients and their caregivers?

Step 4: How will stakeholders be involved?

All study teams—even those in basic and clinical sciences—have experience working with independent peers who review study protocols and manuscripts. This is a form of stakeholder engagement, in which external researchers with an interest in safeguarding the ethical conduct and rigor of research use commonly held standards to review the proposed or completed work. Engagement with other stakeholders is similar. The research team needs to think jointly about research and engagement activities. The first step is to sketch out your research project from first research activity (pre-funding) to last research activity (post funding). The next step is to prioritize among these research activities for engagement. Next is to figure out what kinds of engagement work are possible, and then to designate what level of intensity that represents.

For instance, engagement might involve forming a panel of stakeholders to consult on or collaborate in some research activity or hiring stakeholders to serve as project staff working on a research activity. Interactions with stakeholders can take different forms, including:

- routine communication channels and interaction opportunities of the research workplace, such as in-person meetings, chance meetings, telephone calls, e-mails, and web-enabled communications.
- specialized communications in person, by telephone, by e-mail, or over the web.
- group communications such as town meetings, or group discussions, and these can also be held in-person or virtually
- public comment periods for research prioritizations or plans, and comments may be collected in writing, electronically, or by telephone.

Following is a list of 20 “generic” research activities.

Research Stage	Generic Research Activity
Preparing for research	Building research capacity of patients and other stakeholders
	Training researchers to work with stakeholders
	Prioritizing evidence gaps
	Choosing research topics
Conducting research	Defining the research question
	Choosing relevant outcomes
	Designing a research protocol
	Defining participant inclusion & exclusion criteria
	Drafting or revising study materials & protocols
	Recruiting participants
	Monitoring patient data and safety
	Collecting data
	Analyzing data
	Identifying findings
	Interpreting findings
	Disseminating results
Using research	Implementing evidence in practice
	Evaluating research
	Evaluating engagement
	Identifying topics for future research

1. Starting with the list above, describe research activities your team will undertake. Add rows if needed. Indicate which of the activities are priorities for stakeholder involvement. Note that it is not necessary to fill in every row. Prioritize rows where engagement can help you meet the intrinsic and instrumental aims that you summarized in Steps 1 and 2.

Research Stage	Research Activity	Priority for stakeholder involvement
Preparing for research		
Conducting research		
Using research		

1. What budget and other resources will your team devote to preparing for, conducting, and using research? What is the total budget?

2. What share of the total budget and resources can be dedicated to engagement activities?
3. What do you know, if anything, about patients' and stakeholders' preferences and availability for involvement in your research?
4. Translate your responses to questions 1-4 into descriptions of what you and your stakeholders will do together, including which stakeholder communities will be involved, what the engagement activity will be, and what level of engagement intensity that represents (from the 4Cs). Expand or alter the table as needed; it is not strictly necessary to engage every community in exactly the same activity or intensity.

Research Stage	Research Activity	Stakeholder communities	Engagement activity	Engagement Intensity
Preparing for research				
Conducting research				
Using research				

1. Summarize the activities and stakeholders in a few sentences.

2. Use the tables on preceding pages or the "map" on the next page to summarize your engagement plan in one or two visualization(s) that may be useful in a research proposal.

Research stage	Research activity	Stakeholder community						
		Patients & public	Providers	Payers	Purchasers	Product makers	Policy makers	Principal investigators
Preparing for research								
Conducting research								
Using evidence								

Worksheet 3. Evaluating Engagement

In this worksheet, three distinct types of evaluation are proposed (1) inventories of engagement work to examine what has been done and by whom (2) procedural evaluations to examine how the work has been carried out, and (3) outcomes evaluations to examine impacts of engagement work on stakeholders and research.

This worksheet takes you through four steps. At the conclusion of this worksheet, consider writing a one paragraph summary of your responses. This summary may suffice to address the engagement requirements of a variety of funders.

It is important to keep in mind that you don't have to collect information on every topic. This worksheet presents an outline from which you can choose the most relevant evaluation topics and measures.

Step 1: Inventory evaluations of the content and context of engagement

Step 2: Procedural evaluations

Step 3: Outcomes evaluations (1) and (2)

Step 4: Visualization of an evaluation plan

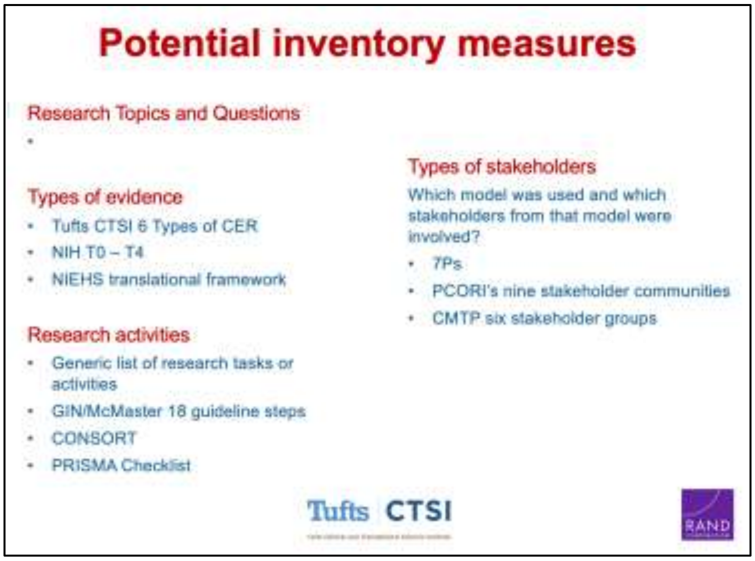
Step 1: Inventory evaluations of the content and context of engagement

To complete this section, answer the following questions:

1. What do researchers report regarding the stakeholder engagement plan or activity?

   Secondary questions may dive into more detail:

   a. With which types of stakeholders do researchers report engagement?
   b. What is the research topic and question?
   c. What type of evidence is the team producing?
      (Instructions: use Tufts 6 stages model https://www.tuftsctsi.org/research-services/stakeholder-community-engagement/comparative-effectiveness-research/; OR NIH translational spectrum https://ncats.nih.gov/translation/spectrum; OR NIEHS translational spectrum https://ehp.niehs.nih.gov/doi/10.1289/ehp3657. Choose one of these evidence models or choose your own and describe where your research is located on the evidence model you've chosen)
   d. In what research activities are stakeholders involved? (Refer back to the evidence map you produced in Worksheet 2)



Potential inventory measures

Research Topics and Questions
-

Types of evidence
- Tufts CTSI 6 Types of CER
- NIH T0 – T4
- NIEHS translational framework

Research activities
- Generic list of research tasks or activities
- GIN/McMaster 18 guideline steps
- CONSORT
- PRISMA Checklist

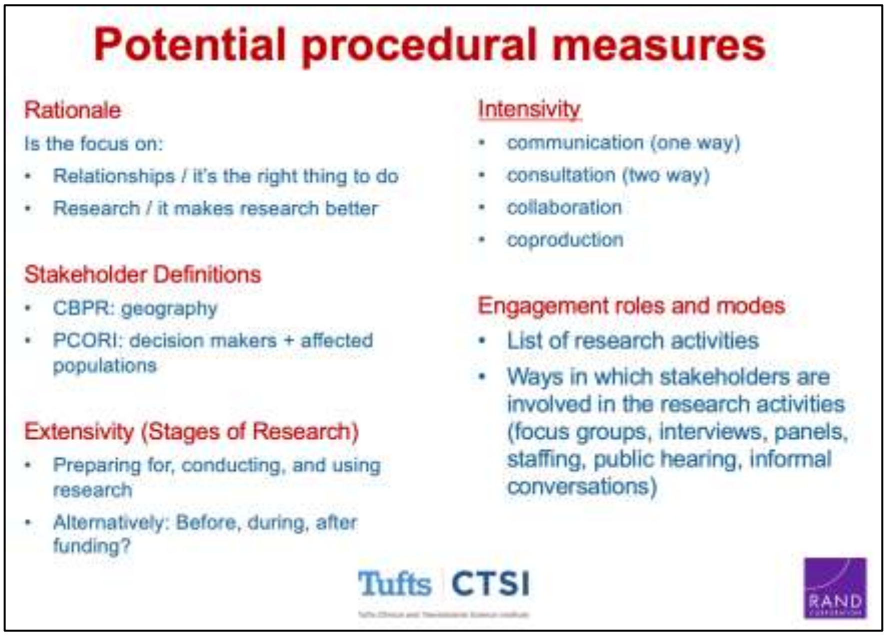
Types of stakeholders
Which model was used and which stakeholders from that model were involved?
- 7Ps
- PCORI's nine stakeholder communities
- CMTP six stakeholder groups

Step 2: Procedural evaluations

To complete this section, answer the following questions:

To what extent have researchers met accepted standards in the engagement of stakeholders?

1. What rationale is presented for engaging with stakeholders? (state the engagement aims and describe whether they are focused principally on intrinsic goods such as better relationships or on instrumental goods such as better research)
2. What definitions of stakeholder and engagement, if any, are presented in the research?
3. Have stakeholders been involved in preparing for, conducting, and using research? An alternative formulation is: Have stakeholders been involved before, during, and after research is funded?
4. What are modes (panels, interviews, staffing, etc) by which stakeholders are engaged?
5. How intensive were the engagement activities?



Potential procedural measures

Rationale

Is the focus on:

- Relationships / it's the right thing to do
- Research / it makes research better

Stakeholder Definitions

- CBPR: geography
- PCORI: decision makers + affected populations

Extensivity (Stages of Research)

- Preparing for, conducting, and using research
- Alternatively: Before, during, after funding?

Intensivity

- communication (one way)
- consultation (two way)
- collaboration
- coproduction

Engagement roles and modes

- List of research activities
- Ways in which stakeholders are involved in the research activities (focus groups, interviews, panels, staffing, public hearing, informal conversations)

Tufts CTSI

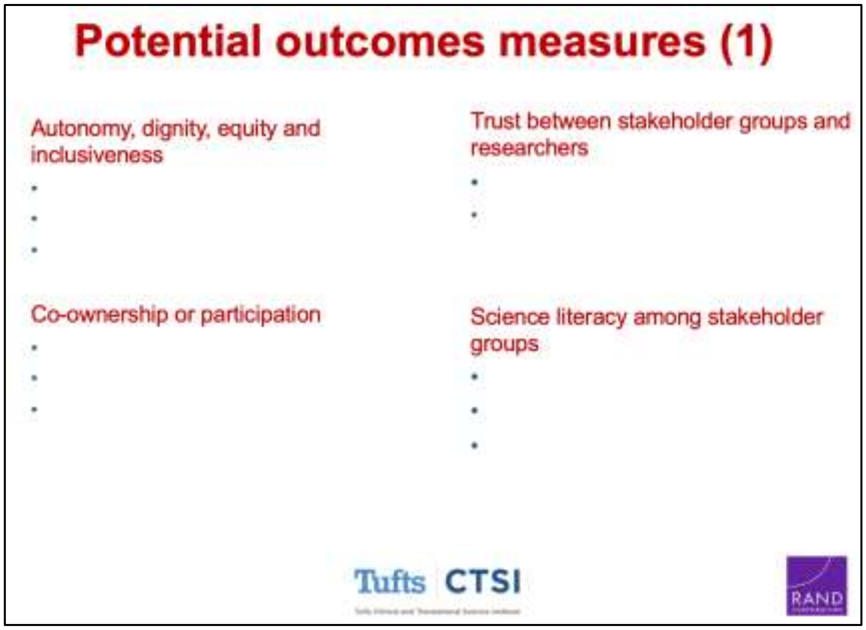
RAND

Step 3: Outcomes evaluations (1) and (2)

<u>To complete this section, answer the following questions:</u>

Outcomes evaluations (1): To what extent has engagement met its intrinsic aims?

1. To what extent do stakeholders report that engagement with a research team improves their autonomy and dignity, equity and inclusiveness, and a sense of co-ownership and participation?
2. Is there evidence of improved trust between stakeholder groups and researchers?
3. Is there evidence of improved science literacy among stakeholder groups?



Potential outcomes measures (1)

Autonomy, dignity, equity and inclusiveness
•
•
•

Trust between stakeholder groups and researchers
•
•

Co-ownership or participation
•
•
•

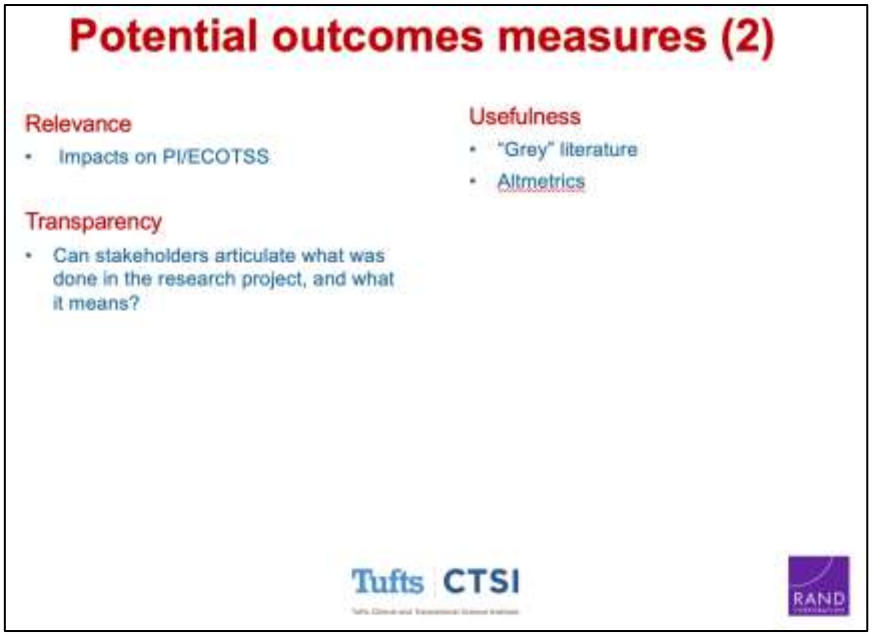
Science literacy among stakeholder groups
•
•
•

Tufts CTSI

RAND

Outcomes evaluations (2): To what extent has engagement met its instrumental aims?

1. Do questions, outcome measures, and other key aspects of the research design change to meet the decision needs of stakeholders?
2. To what extent can stakeholders who were involved in the research articulate what was studied, how, and what the findings are, and how they might be applied in practice?
3. To what extent is research evidence used to support decision making?



Potential outcomes measures (2)

Relevance

- Impacts on PI/ECOTSS

Transparency

- Can stakeholders articulate what was done in the research project, and what it means?

Usefulness

- "Grey" literature
- Altmetrics

Step 4: Visualization and summary of an evaluation plan

To complete this section:

1. Fill in the table below from material you developed in previous steps

Measure Domain	**Measure Topic** (choose some of the numbered items in each step of this worksheet)	**Measure** (choose some of the bulleted items in slides above)	**Data** (identify data you will collect to address the topic)
Inventory			
Process			
Outcomes			

2. Write a 3-5 line summary of the material you developed in previous steps.