Appendix D: Environmental Scan Search Strategy

Targeted Search Strategy

Searches of targeted sources were limited to citations published after 2005. Sources searched in the health field included the Cochrane Library (Cochrane Reviews, other reviews, and methods studies), Agency for Healthcare Research and Quality, Veterans Administration Technology Assessment Program, Commonwealth Fund, Kaiser Family Foundation, National Academy for State Health Policy, Robert Wood Johnson Foundation, and the following journals: *Health Services Research, Health Affairs, Health Expectations, Health Education & Behavior,* and *Health Promotion Practice.* The following search terms were used: citizen engagement, citizen jury, community based participatory research, comparative effectiveness, deliberative democracy, guideline development, information dissemination, participatory research, patient-centered, patient engagement, patient involvement, research method, service user, and stakeholder participation.

The key source searched for the business field was the *Journal of Business Ethics* using the search term, consumer engagement, consumer involvement, customer engagement, and stakeholder engagement. In the field of public and civic engagement, the *Journal of Public Deliberation* and the Kettering Foundation website were searched using the terms citizen engagement, citizen involvement, consumer engagement, engagement method, participatory research, service user, and stakeholder engagement. The environmental and planning fields were searched through a Google search five pages deep and in the following journals: *Environmental Management, Environmental Quality Management,* and *Journal of the American Planning Association.* Search terms included citizen engagement, citizen involvement, citizen participation, engaging community, public input, public involvement, public participation, service user, stakeholder engagement, and stakeholder involvement. In the field of corrections, a Google search was conducted, five pages deep, and the *Journal of Criminal Justice* and *Journal of Correctional Health Care* were searched using the terms consumer engagement, consumer research, inmate engagement, inmate involvement, participatory research, patient engagement, patient involvement, prisoner involvement, prisoner research, service user, and stakeholder engagement. Both the education and social services fields were searched in Google, five pages deep, and the *Journal of Planning, Education, and Research* and *Journal of Social Services Research,* respectively, using the terms consumer engagement, consumer involvement, citizen engagement, public engagement, public involvement, public participation, stakeholder involvement, stakeholder participation, and stakeholder engagement.

References for relevant Cochrane systematic reviews were hand searched for relevant citations from the last 10 years. References from other systematic reviews were hand searched for citations from beyond health. Additionally, references related to Health Technology Assessment programs previously identified by the Center were assessed for relevance and included as appropriate.
**MEDLINE Search Strategy**

A MEDLINE search was conducted to identify other potentially relevant references. Titles and abstracts were reviewed for relevance. The Medline search yielded a total of 835 abstracts, with 58 abstracts being selected as relevant. The search was limited to review articles published after 2006. Abstracts were excluded if the full article was not available in English. Citations were included based on relevance to the research questions, and date of publication. Studies were excluded if they were not relevant to the research questions, if no abstract or full article was available, and if they were not published in English.

Database: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) <1946 to November Week 2 2011>
Search Strategy:

```
1 ((patient$ or care$ or stakeholder$ or communit$ or consumer$ or citizen$ or service user) adj2 (engagem$ or involvem$ or participa$)).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier] (58069)
2 exp Consumer Participation/ (28179)
3 exp Technology Assessment, Biomedical/ (8560)
4 exp Patient-Centered Care/ (7853)
5 exp Community-Based Participatory Research/ (970)
6 exp "Outcome Assessment (Health Care)"/ (563302)
7 exp Comparative Effectiveness Research/ (583)
8 exp Practice Guidelines as Topic/ (65556)
9 exp Information Dissemination/ (7705)
10 exp Access to Information/ (3423)
11 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (672475)
12 1 and 11 (33314)
13 limit 12 to (yr="2007 -Current" and "review") (835)
```
Appendix E: Expert Interview Guide

Introduction

Interviewer:
Hello (stakeholder name), this is (interviewer name) from the Center for Evidence-based Policy in Portland, Oregon. I’m calling on behalf of the Patient Centered Outcomes Research Institute or PCORI to conduct the expert stakeholder interview we have scheduled for today.

► Is this still a good time for you to talk?

Interviewer:
Great! Thank you so much for agreeing to participate in this interview today.

Before we get started, I’d like to provide some background on PCORI and to tell you about the project we are doing.

► But before I do that, it would be helpful to know if you are familiar with PCORI or if you need me to give you a bit more background about the Institute. How familiar are you with PCORI?

If Participant is familiar with PCORI skip to description of project only.

PCORI is a new national agency that was established by (the US) Congress through the 2010 Patient Protection and Affordable Care Act. One of PCORI’s main objectives is to ensure that the views of patients are central in all of its research activities. To this end, the PCORI Methodology Committee is working to identify and to develop methodological standards to include the patient perspective into three main areas of research, namely:

- The development and prioritization of research questions
- The design of study components, such as (?) the selection of interventions, comparators and outcomes (including patient-reported outcomes)
- The processes of clinical decision-making and the delivery of care.

We know that the published literature can tell us only so much about including patients’ perspectives in patient centered outcomes research (PCOR). As a result, PCORI has commissioned these interviews with experts such as you in order to help identify effective methods and best practices in this field. The findings from these interviews, along with a companion literature review, will inform the writing of a Methodology Report that will be submitted to Congress and that will guide the work of PCORI as it moves forward. As part of
the project, we have identified and invited national and international experts in patient and public engagement.

I expect that our interview today should take about 30 minutes - depending on how much information (and time) you have to offer. The questions I'll be asking were developed in consultation with PCORI staff and with some of the members of the Patient Centeredness Work Group of the PCORI Methodology Committee.

► Before we get started, do you have any questions for me?

**Interviewer:**

If you agree, I would like to audio-record our interview today. This is only for reporting purposes and for accuracy in analyzing the interviews. In the report, we won’t directly associate any of your comments to you as an individual. If we do use a quote as an illustration in the final report we will only say that it comes from a member of a particular stakeholder group such as a health care provider, research professional, or patient advocate. All recordings will be destroyed at the end of the data collection and reporting process. If you prefer not to be audio-recorded that is fine as well and I will record your comments by hand.

► Do I have your permission to audio-record the interview?
  - Yes
  - No

**Questions**

**Interviewer:**

1. Okay great, I'd like to start with asking about your experiences with patient engagement. In particular, we would be interested in hearing your thoughts about when and under what circumstances is it most appropriate to engage patients in research activities? And just to provide context we are asking about any and all types of research you may have conducted including clinical research, comparative effectiveness research, ethnographic or community based research or any other research traditions that you have been involved with.
   - PROBE: For example, there are varying opinions about when it’s appropriate for patients to participate in the different steps in complex research processes. What do you think about this?

2. Thank you. PCORI would like to know about which practices are currently being used by experts in patient involvement - and we’d like to hear about your experiences with patient engagement in
the work that you do. For instance, what methods have you found to be the most effective when it comes to engaging patients?

- PROBE: Are there any particular ‘best practices’ sources that you rely on when designing patient engagement activities?
- PROBE: Do you have any particular methods you use to reach under-represented patient groups or hard to reach patients?
- PROBE: How do you support patients during the process?

[If the respondent has already offered specific stories in his/her answers above, skip to Question #4]

3. Super, thank you. I’d really appreciate hearing about some specific examples from your experience of patient involvement. Could you tell me about a time that your work with patients in a research project was particularly successful? What elements of the process were essential to that success?

- PROBE: How would you define successful engagement?
- PROBE: How did you identify and recruit the participants?
- PROBE: Can you also tell me about a time that your work engaging patients/the public was particularly challenging. If you had it to do over again, what would you do differently?
- PROBE: In your opinion, what are the main barriers to incorporating the patient perspective in research?
- PROBE: What opportunities do you think would have been missed if patients were not involved?
- PROBE:

4. Thank you, you’re sharing of these experiences and views have been very helpful. My next question has to do with priorities. Do you have any thoughts about what are the top three elements of your process that must be included in order to elicit the patient perspective in research activities?

- PROBE: For example, some literature suggests that proper preparation of non-traditional stakeholders is essential to successful engagement. What do you think about this?
- PROBE: Another example might be making sure everyone on the research team is on equal footing, e.g. no use of titles such as ‘Dr. Jones’ in discussion groups or making sure the chair of the committee is committed and trained in egalitarian facilitation methods.
PROBE: How do you ensure that patients understand the clinical context and research issues in order to best incorporate factors or issues that are of greatest importance to them in decision-making?

5. Thank you. Now I would like to change the topic and to ask about your views on patient surrogates – in other words, people who provide information on behalf of patients but aren’t patients themselves (such as a family members, clinicians, or other sorts of patient representatives). I’d like to hear your thoughts on the appropriate use of patient ‘surrogates’. First of all, have you worked with patient surrogates in your work?
   - PROBE: In your opinion, what methods, if any, are effective in determining whether other stakeholders such as clinicians or advocates, accurately reflect the patient’s perspective?
   - PROBE: Do you provide different preparation for surrogates than for patients?
   - PROBE: If you haven’t worked with them, why not? - Would you? – If so, how would you identify them?

6. Thank you very much. We really appreciate your views and your participation. Those are all the questions I have today. Do you have anything you would like to add?

7. One final request we are making of everyone we interview is to refer us to any other colleagues or experts that we should be speaking to about this topic. We are looking for names of anyone that you feel we simply must speak to if we are to get a comprehensive view of the best practices in patient engagement. Can you think of anyone we should speak to?
   - PROBE: Do you happen to have their contact information?

**Interviewer:**

I want to extend our thanks and those of the PCORI Methodology Committee for taking the time today to talk with us. Your expertise is invaluable to the work of PCORI and its efforts to engage patients in research design and execution. The information you and others have provided will be used to inform the writing of a mandated congressional report on best practices in patient engagement. We will notify you when the final report is available to the public.
Appendix F: Facilitated Discussion Guide

Project Overview
The Center for Evidence-based Policy (Center) has been awarded a short-term contract from the Patient Centered Outcomes Research Institute (PCORI). The institute was established by Congress through the 2010 Patient Protection and Affordable Care Act to help patients and providers make more informed, evidence-based healthcare decisions. Under this contract, the Center will collect and analyze diverse perspectives on how best to effectively engage the public and incorporate the patient voice in patient centered outcomes research. This will be done through telephone interviews with prominent experts in the field of patient and public engagement and through a series of focused discussion groups with the general public. The Center is partnering with the University Network Group for Collaborative Governance (UNCG) and the Policy Consensus Initiative (PCI) to conduct the discussion groups.

Patient Centered Outcomes Research (PCOR)
Individuals (patients, physicians, and policy makers) and groups (insurance companies, Medicaid departments, and hospitals) are making important decisions about health care treatments and interventions every day whether or not they have research information. Providing these decision-makers with the best available scientific evidence supports their ability to make the best possible health care decisions. This is the focus of patient centered outcomes research (PCOR).

PCOR is research that is informed by the perspectives, interests and values of patients throughout the research process, from the selection of research questions to the dissemination of research results. This research also includes bridging information gaps about what works and what does not work in health care services and by identifying important areas for future research. Patient-centered outcomes research is intended to be practically relevant. Its real-world impact on patients is known and included in decisions about prevention, diagnosis and treatment. For example, when designing research to study the effectiveness of cholesterol medicine, doctors may be most interested in a clinical outcome, such as changes in the ratio between ‘good’ cholesterol and ‘bad’ cholesterol. Whereas patients might be concerned with quality of life outcomes such as what side effects the medicine has.

PCOR helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions:
1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can the health care system improve my chances of achieving the outcomes I prefer?”
To answer these questions, patient centered outcomes research:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.²

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed health care decisions and improve health care delivery. PCORI will commission research that is guided by patients, caregivers and the broader health care community and will produce high integrity, evidence-based information.

**Patient Engagement**

Patient stakeholder engagement is one of the core objectives for the PCORI. Increasing the exchange of knowledge between researchers and other stakeholders has many benefits for research processes and products. According to Gooberman-Hill and Horwood (2008) “Awareness of the difference between the views of members of the public and those of researchers and professionals implies a pressing need to include the public in setting research agendas at the early stages in the research process . . . . Involving members of the public at this stage may be key to real empowerment as it is at these stages of research development that there is opportunity to influence.” Involving stakeholders early in the research process provides a meaningful opportunity to help guide the development of research questions and subsequent research products. Stakeholders are able to provide real-world context for research, which increases its relevance, as well as usability. Additionally, stakeholders are more likely to take ownership and participate in the dissemination of end products if they have had an active hand in shaping the topic, the questions, and the focus of the research.

Traditionally, involving stakeholders in research has meant communicating questions or problems in the beginning phases and communicating results at the end of that research (Burger, Gochfeld & Pletnikoff, 2009). PCORI, however, is trying to identify effective methods to engage patient stakeholders throughout the research process. Researchers want their work and resulting products to be utilized, but they sometimes lack information regarding the context and subtleties facing patients and other decision-

² Definition of patient centered outcomes research adopted by PCORI, 2011
makers. Similarly, patients and other decision-makers need to know which research products are applicable to the dilemmas they face, but they sometimes lack knowledge about which questions the research addresses, which research is reliable, and how to incorporate research findings into decision making.

**Identification and Recruitment of Participants**

Identification and recruitment of participants for the PCORI Expert Interviews Project should be accomplished using standard community-based recruitment strategies. Below is a list of steps that may be followed and modified for your specific community. These are not exhaustive and should be used as a guideline for getting started. The Center for Evidence-based Policy has developed general recruitment materials (flyers, posters, announcements) that can be modified for specific site and community needs (Attachments B-D).

**Participant Recruitment**

1. Contact local organizations with which you have worked in the past and ask if you may distribute or post recruitment materials at their site. Focus recruitment efforts on organizations that display public materials and have a high volume of foot traffic such as community centers, senior centers, family practice clinics, community clinics, county health clinics, churches and non-profit organizations that may be good sources of people who are interested in participating in health services research.

2. Distribute flyers, blurbs and other recruitment materials widely. Be sure that all relevant IRB numbers are included on the materials before distribution. See templates in the materials packet sent under separate cover.

3. Make public announcements at health forums, public meetings, exercise programs, or other appropriate venues where people gather to learn about health or research.

4. Contact local organizations with which you have worked in the past and ask if they will post an announcement in their newsletter.

5. Consider placing ads in local daily or weekly newspapers.

6. Post an announcement on your local internet information sharing sites (such as Craigslist) using the template provided in your training materials.

**Participant Screening & Scheduling**

1. Screen participants for age requirements.

2. Ask if participant works for a patient organization or advocacy group.

3. Advise participant of intent to audio record meeting.

4. Advise participants of time commitment (up to two hours for discussion group).
5. Record volunteer's name and all contact information including telephone, email and message phone (if available) into a spreadsheet and store securely in compliance with IRB regulation. If possible, record how they heard about the opportunity.

6. Inform participants of the time, place and logistics for participation (length of discussion time, parking or transit information, incentive type and amount, etc.).

7. Answer any questions they may have about the project or PCORI in general. If they have extensive questions, please refer them to Samantha Slaughter-Mason at slaughsa@ohsu.edu.

8. After reaching 12 participants per discussion group, close recruitment but continue to take information for up to 5 more alternates for each group. Alternates and additional volunteers who call after recruitment is closed should be directed to the PCORI website for other opportunities to participate in providing feedback to the Institute.

9. Make reminder calls the day before the event. Give participants the date, time, location, and address.

**Meeting Preparation**

An effective facilitator spends time in thoughtful preparation for the meeting, with specific attention to meeting materials, participant presentations, meeting dynamics and follow up needs and documentation. Preparation includes identifying, in advance, the methods and tools that will be used, or that need to be provided to participants. The following questions and tasks should be considered when preparing for the meeting:

**Purpose**

- Is the purpose of the overall project and the discussion group clear to the facilitator?
- How will the facilitator communicate the meeting objectives to the participants?
- Record the objectives and hand them out or include on flip charts (the Center will be providing posters with objectives and ground rules for all sites).

**Participants**

- Who are the participants?
- How will participants be oriented?
- Do any participants have special needs that require accommodation?
- What is the size of the group, and how will the size affect process design?
- How will participants be introduced to one another?
- Is the facilitator clear about the role of all the meeting participants (e.g. patients, facilitator and local staff, Center)?

**Process and Possible Dynamics**

- What are the potential problems with the meeting? How can they be addressed in advance?
✓ How will ground rules be communicated? (use poster provided by the Center)
✓ How will participants be invited or expected to participate? For example, will they be called upon (and in what order)? Will all participants respond to specific or general questions? What techniques will be used to ensure all voices are heard?
✓ Which meeting facilitation tools (see next section) will be used? How will these be prepared and communicated to participants?

Planning for Logistics
✓ Is the meeting scheduled at a time convenient to all participants? (For example, participants may have full-time jobs or family responsibilities that limit participation. What flexible options can accommodate busy schedules?)
✓ Do any participants require special accommodations? How will they be made available should they be necessary?
✓ How much time is needed to accomplish the meeting objectives?
✓ When and where will the meeting be held?
✓ How will participants be informed of meeting location, date, time, etc.? Who will send the information to participants? Who will send a reminder 24-48 hours before the meeting?
✓ What materials need to be prepared in advance? Who will prepare and assemble the materials?
✓ Are materials available in a format that is accessible for all participants?
✓ What is the plan for summarizing the meeting, and submitting data?
✓ How will registration be handled (including completion of demographic information and distribution of incentives)?

Materials
✓ Review checklist of all materials that will be needed on site (Appendix A).
✓ Purchase gift cards or requisition petty cash.
✓ Test recording equipment and replace low batteries or purchase and bring spare batteries.
✓ Print enough copies of all written materials for all participants.
✓ Purchase or order food and beverages for participants.

Thoughtful preparation and planning can help avoid most meeting pitfalls, but facilitators will not always be able to anticipate every participant need, dynamic and nuance. The real job begins when the meeting starts. It is the role of facilitator to recognize problems as they arise, and respond immediately and appropriately.

At the Meeting: Focus and Staying on Track
Just as important to preparation is the ability to keep participants focused and on track during the meeting. Some of the “focus” work can be done in the preparation stage, by ensuring that all participants understand the purpose of the meeting and come prepared to participate. Making sure participants
understand the purpose of the meeting and any ground rules provides a foundation for the facilitator to keep the meeting focused and on task. To effectively maintain the course of the meeting, the facilitator will need to pay attention to both the process and the content of the meeting. The goal of the facilitator is to stay on track and balance participation (process) with meeting results (content) so that both are as supportive as possible to participants. The following steps can provide guidance:

1. Introduce the meeting purpose and participants (in general), referring to each participant as an “expert” in his/her role and experience related to the topic.
2. Ask all participants to introduce themselves, and say a sentence about why they agreed to participate.
3. Review the meeting purpose and ground rules.
4. Orient participants to their role and the roles of the sponsoring organization and other partners.
5. Indicate any other discussion guidelines the facilitator intends to use (such as no acronyms).
6. Use visual or verbal summaries to manage information flow (see below).
7. Interrupt the discussion as necessary to refocus and keep it on track (see below).

**Process Interruptions**

Occasionally, it may be necessary for the facilitator to interrupt the discussion in order to refocus participants or rebalance interactions. The field of facilitation refers to this as a “process intervention.” Most often, such interventions by the facilitator can simply refer back to the meeting purpose, objectives or ground rules. Some common concerns or situations requiring facilitator interruption include:

- Side-bar conversations
- Staying on time
- Staying focused on the agenda topic
- Run-on discussions
- Conflicts of interest or biases

The following techniques may be useful when a facilitator finds it necessary to interrupt the discussion. Use of gentle humor may be helpful in utilizing the following techniques. In all accounts, apply a positive, friendly tone that treats participants with respect.

**Side-bar Conversations**

- Specifically re-focus on a particular topic or reference a particular agenda item.
- Use a “parking lot” to capture issues that need to be addressed, but which are not the focus of the meeting. Include these in the analysis submitted for the project.
- Ask questions about relevance to the topic.
- Make eye contact or use the person’s name. Make a direct and personalized request.

**Staying on Time or Dominant Participant**

- Specifically re-focus on a particular topic or reference a particular agenda item.
✓ Use a “parking lot” to capture issues that need to be addressed, but which are not the focus of the meeting.
✓ Keep things moving
  ► “We appreciate your input, but let’s keep things moving. Does anyone else have a response?”
  ► “Thank you for your comments and for sharing your perspective. Does anyone else have something to add?”
✓ Indicate the need to close the discussion on time, after giving a five minute “time warning.”
✓ Ask what needs to be covered in order to conclude the discussion.

Staying Focused on the Agenda Topic
✓ Reference the objectives, ground rules, or other preparation materials.
✓ Specifically re-focus on a particular topic or reference a particular prompt.
✓ Use a “parking lot” to capture issues that need to be addressed, but which are not the focus of the meeting.
✓ Set boundaries, but validate participants’ contributions.
  ► “I hear that you are frustrated that this issue is not the purpose of this meeting and that it is important to you. Perhaps I can have someone call you to discuss your concerns further after the meeting so that we can make sure we get to all of the agenda items.”
✓ Offer solutions and ask the group for validation or support.
✓ Ask questions about relevance to the topic.

Run-on Discussions
✓ Re-focus on a particular topic or reference a particular agenda item.
✓ Summarize the discussion and key points made by participants to ensure participants feel their perspectives are heard and allow for clarification
  ► “So far, what I have heard you say is . . . . Is that accurate?”
✓ Put the process on hold and take a break.
✓ Ask questions about relevance to the topic.

Conflicts of Interest, Bias, or Discord between Participants
✓ Reference the purpose statement, ground rules, or other preparation materials.
✓ Set boundaries, but validate participants’ contributions.
  ► “I hear that you are frustrated that this issue is not the purpose of this meeting and that it is important to you. Perhaps I can have someone call you to discuss your concerns further after the meeting so that we can make sure we get to all of the agenda items.”
✓ Encourage less vocal stakeholders to share and participate by recognizing their value to the group.
  ► “[Name], do you have any feedback? Your expertise as a patient is very important to the topic.”
“[Name], we have not heard from you, what are your thoughts related to this question? Are we capturing what is important to you?”

- Put the process on hold and take a break.
- If participants seem critical of each other, use verbal discussion summaries to move discussion to an idea and away from a person.

**Visual or Verbal Discussion Summaries**

One of the key elements to successful facilitation is managing all the information the participants are producing with their discussion, as well as the information to which they are reacting. It is the facilitator’s role to ensure that all participants understand what is going on, what is being discussed, and what is being suggested or agreed to. It is also the facilitator’s role to accurately capture, describe and summarize this set of information for participants and the larger project.

One common method is to keep a running tally of comments, ideas, discussion, and agreements by using flip charts, computer projections, or other visual techniques. The advantage of this method is that participants can “see” what is going on, and can help ensure the facilitator is accurately capturing their discussion. Some facilitators use a note-taker to keep track. This frees the facilitator to focus on group dynamics, staying on task, meeting processes and other aspects of facilitation. Others prefer to have more direct control over what is recorded. Either way, capturing information at the right level for the meeting purpose, summarizing without substantively changing input, or knowing when to summarize or ask for clarification are all important.

Facilitators should use tools and techniques that work best for them, the participants and the meeting logistics. The following techniques may be useful in managing and summarizing participant discussion.

- Write it down and hang it on the wall, or use a visual electronic tool that all participants can see.
- Work on one issue at a time.
- When someone offers an idea or suggestion, write it down. If it is offered again (by the same participant, or someone else), refer or point to it. Adjust as necessary.
- If a participant seems critical or disrespectful of another participant, point to an idea and redirect away from a person.
- If appropriate, further develop an idea that has been listed using qualifications, additions, etc.
- Write down and or repeat group agreement or consensus.
- When the group gets off track, write down the side bar issue.
Moderator Guide

Welcome
Hello everyone. Thank you so much for coming today. We are going to get started now. Please feel free to continue eating and drinking while I talk. My name is [insert facilitator name here] and I work with [insert affiliated University Name]. We were invited to facilitate this group discussion today by the Center for Evidence-based Policy (Center) at Oregon Health & Science University (OHSU). [Insert names of Center staff here] from the Center are here with us today and will be observing the discussion and if needed they will help us if questions come up about the project. In just a few minutes I will ask all of you to introduce yourselves and will give you an opportunity to ask questions before we get started with the formal discussion but right now I want to go over a little background on the project and our process and goals for today.

Background & Introduction: (Handout: PCORI Information Sheet)
Individuals (patients, physicians, and policy makers) and groups (insurance companies, Medicaid departments, and hospitals) make important decisions about health care treatments and interventions every day whether or not they have good research information to help with those decisions. Providing people with the best available scientific evidence can help them to make the best possible health care decisions. This is the purpose of patient centered outcomes research (PCOR). And, this is why we are talking with you today.

PCOR is research that is informed by the views, interests and values of patients throughout the research process, from the selection of research questions to the distribution of research results. This type of research also includes looking for answers about what works and what does not work in health care services. Patient-centered outcomes research is meant to be practical and meaningful to patients at the time that they are making health care decisions. For example, a patient diagnosed with high cholesterol may be thinking about taking medication for the condition. When trying to decide which medication is best, the patient might be most concerned about preventing a heart attack. Their doctor might be focused on what we call a clinical outcome such as improvement in the ratio of good cholesterol to bad cholesterol. Both pieces of information may be important, but the ‘patient centered outcome’ is the information that is identified as most important to the patient.

Suggestion: (Have Center staff introduce this section on the project and PCOR)

The Patient-Centered Outcomes Research Institute (PCORI) was established by the US Congress through the 2010 Patient Protection and Affordable Care Act. This new institute is funded through the US government but it is not part of any federal agency or department. This allows PCORI to work efficiently
and independently to produce high quality research. By including a wide range of people in their research activities, such as in this focus group tonight, PCORI will be able to provide answers to the questions that are most important to patients when they are making healthcare decisions.

One of PCORI’s main goals is to make sure patients’ questions and concerns are central to all of its research activities. PCORI is in the process of writing a ‘how to’ manual that will guide all of their national research work going forward. That is why we have invited you here today. PCORI wants to hear from you, how best to include patients in all of the work they do.

**Objectives: (Ground Rules Poster)**

Our objectives today are:

- To explore and record ideas of how best to involve patients in research (refer to Example Research Process Poster)
- To explore and record ideas of ineffective approaches to patient involvement
- To determine the best way to find and recruit patients

For the purposes of this discussion, we are going to assume a broad research topic has already been identified and prioritized. For example, imagine that researchers, with the help of a committee of patients, have decided to study diabetes medicines for Type 2 diabetics. Tonight we want to hear from you your ideas about how best to include patients in:

- How to write research questions
- How to decide who are the important groups to study
- What types of treatments should be studied
- What health or quality of life issues are most important to patients
- Which settings or locations make a difference for treatment
- Where and when the study should be done
- How the study results should be disseminated to patients, and what should be included
- How to identify research gaps or new areas for study
- Addressing the benefits and risks of research participation
- Determining protections such as maintaining confidentiality
- Translation and implementation of information to clinicians

In our discussion, we will focus on “how” best to involve patients in these research activities.

- Are there any questions about the objectives for this discussion?
Process & Ground Rules: *(Ground Rules Poster)*

Let’s talk for a couple of minutes about our process and a few ground rules that will help us accomplish our goals. First, I will start off the discussion by asking some questions. I may ask for more specific information along the way.

- There are no right, or wrong answers
- Share your views even if they are different from what other people are saying
- Be respectful of your fellow participants
- Speak one at a time. Let people finish what they are saying before you begin to speak
- Do not talk with your neighbor while someone else is speaking to the group
- Respect each other’s privacy
- Do not repeat what you hear outside of this meeting
- Speak only for yourself and let others do the same

▶ Are there any questions about the discussion process?

Permission to Audio Record

We will be recording the session today in addition to taking handwritten notes because we do not want to miss any of your comments. Later, we will use the recording and our notes to write a report for PCORI.

We will be on a first name basis during the discussion today. Later on when we transcribe the recording we will not include names. Once we are finished writing our report we will destroy the recording. We will maintain your confidentiality. No one will know that an individual comment or story came from you personally.

If anyone wishes not to be audio recorded you are free to leave now. You may take your (incentive payment/gift card) as a thank-you for taking the time to come out today, no explanation is necessary. This process is completely voluntary.

▶ Is it ok to record now?

(If anyone objects to being recorded thank them for their time and willingness to come out. Let them know that there are other opportunities to participate in PCORI activities that do not require audio recording and invite them to contact the institute. Also make sure they have a copy of the PCORI information sheet which includes web address and email contact information.)

Our session will last about 90 minutes. Let’s begin.
Questions
Introduction Question

► We’ll start by going around the room one at a time. We would like you to introduce yourself by telling us four things:

1. Your first name;
2. Whether or not you have ever been involved in any research projects in the past. These may include telephone surveys, focus groups, interviews, online surveys or medical research. We are interested in hearing about all of your experiences with research, not just medical research. (You can simply say you have or have not had previous experience because we will be speaking more in depth about this in just a few minutes);
3. If you are active in a patient organization or work in the area of patient advocacy; and
4. Why you decided to participate in this discussion.

► Would anyone like to start or should I call on someone?

(If no one volunteers the facilitator will call on someone to start. If necessary, the facilitator can continue this process until all have been introduced.)

Topic 1: Past Experiences (Example Research Poster)

The facilitator can offer specific examples for each stage of the research process using the poster as a guide.

► Thank you very much. Now I would like to shift the conversation to the types of experiences you have had, if any, in research design or other research activities. You do not need to share any personal health information unless you want to. We really just need to hear about the types of research activities you have participated in. And remember, when we say research, we are not speaking only of medical research, but we are also interested in hearing about any types of research including market research. Examples of this might be answering questions about your media use on a telephone interview, or reaching out to help people get immunized as part of a community immunization campaign, or maybe you have participated in a group discussion like this one for either a health topic or market product. Please feel free to speak about all types of research activities you have participated in.

Probe: What experience have you had in helping to design research studies?

Probe: What experience have you had in identifying research questions or identifying research priorities?

Probe: What experience have you had in helping to share findings from research activities?
**Probes:**

- Please refer to the sample research activities posted on the wall for additional ideas.
- What would you like PCORI to know about these experiences?
- What about these experiences do you think worked well?
- What did you find frustrating or challenging?
- How did you hear about opportunities to participate?

(If no one volunteers to speak, the facilitator will call on someone to begin the discussion. If necessary the facilitator can continue this process until all have spoken on the topic.)

**Topic 2: Patient Engagement**

- Thank you very much. Now that we have heard about the various experiences you have had with research activities we would like to hear your ideas about what is appropriate patient or public engagement. Can you please share your thoughts about when it is most appropriate to engage patients or the public in research activities? Is there ever a time when it might be inappropriate to engage the public?
  - Please refer to the sample research activities posted on the wall.
  - What role do you see for patients and the general public in these activities?

(If no one volunteers to speak, the facilitator will call on someone to begin the discussion. If necessary the facilitator can continue this process until all have spoken on the topic.)

**Topic 3: Effective Approaches to Engagement**

- Okay, great. Thank you for sharing that information. Now we are going to move on to our final topic of discussion today. We are interested in hearing about approaches you think researchers should use in order to successfully involve patients and the public in this research?
  - What do you think researchers should or could do to ensure successful patient involvement in these activities?
  - Are there any approaches that you feel would not be effective or that you would find distasteful, offensive or uncomfortable?
  - How do you recommend identifying patients to participate?
  - What processes or activities do you think would be successful for engaging patients? Why?
Closing
Thank you so much for coming out today to talk with us. Your time and thoughtfulness are greatly appreciated. If you would like to be sent information about the final report please leave your contact information with (names of Center staff) and they will send you an email with a link to access the report when it is made public. You may also take (names of Center staff) business card with contact information in case you have questions in the future. You may want to visit PCORI’s website to look for additional opportunities to participate in this kind of research. (Refer them to PCORI handout given at the beginning of discussion.)
Data Analysis & Transfer

After the completion of facilitated discussions, the PCI/UNCG team at each location will conduct initial analysis of data. Further, in-depth analysis across all locations will be conducted by Center staff. Data to be submitted to the Center from PCI/UNCG, within one week of each discussion, includes:

1. A narrative report of key findings, written and submitted by each site via a secure web service (Zoomerang); and
2. Rapid transcription of audio recordings.

Prior to Discussions

Prior to your scheduled discussions, you will receive an email with links to three surveys: Group 1, Group 2, and Summary. You will submit three surveys total, one for each individual discussion group and one containing an overall summary of both groups. You will also receive a copy of the Data Entry Template and this user guide. Please take time to review both documents prior to your discussion group if possible to ensure you are prepared to organize and summarize the results of your discussions. These summaries are required within one week of the second completed discussion group at your location.

Preparing Data

After you have completed your discussion groups you should prepare your discussion summary. It is not expected that you will have discussed every specific question within each topic area. Please enter the discussion points in the entry field they are most relevant to. You are providing an initial analysis and organization of the data.

The Data Entry Template provides you the best way to prepare for entering data into the survey. There is a 3000 character limit for each field, and this limit is enforced in the Template. It provides you the framework for organizing your information into the fields that will be available during the survey process.

The surveys for the Group 1 and Group 2 discussions follow the subsequent framework:

- Identification and characteristics of your discussion group
- Three key topics
  - Past experiences
  - Patient engagement, and
  - Effective approaches to engagement.
- Summary of up to three key themes that emerged during discussion
- Summary of up to two areas of consensus
• Summary of up to two areas of disagreement, and
• An assessment from the facilitator perspective

The surveys for the Summary of both discussions follow the subsequent framework:
• Identification and characteristics of your discussion group (to match with individual groups)
• Description of methods
• Summary of up to three key themes that emerged across discussion, and
• An overall assessment from the facilitator perspective

Key things to keep in mind while preparing your summary:
• There is a 3000 character limit in each field, any data entered beyond this will not be received
• Please organize your information by the three key topics
• Please use your recordings and/or transcriptions to clarify any important discussion points you may be unsure of

Facilitated Discussion Data Template

Facilitated Discussion Data Summary: Group 1

Group Information
What was the date and start time for the discussion group?
Who facilitated the discussion?
Where were the discussion groups held? (institution, city, state):
How many women participated:
How many men participated:

Introductions
How many participants had been involved in previous research?
Were any participants active in patient engagement or advocacy? If yes, please describe.
Why did participants decide to participate in the discussion groups?

Topic 1: Past experiences
Experience with designing research studies?
Experience with identifying research questions or priorities?
Experience with sharing findings from research?
What worked well?
What was frustrating or challenging?
Other discussion under this topic?

**Topic 2: Patient engagement in research activities**
When is it most appropriate to engage patients?
What role is there for patients and the general public?
What processes might be successful in engaging patients?
Other discussion under this topic?

**Topic 3: Effective approaches to engagement**
What should researchers do to successfully involve patients and the public in research?
What should researchers do to ensure successful patient involvement?
What approaches would not be effective or might be distasteful or offensive or uncomfortable?

How should patients be identified?
What should be included in PCORI’s patient engagement strategy?
Other discussion under this topic?

**Results by Theme**

**Key findings**
Theme 1:
Theme 2:
Theme 3:

**Areas of consensus**
Theme 1:
Theme 2:

**Areas of disagreement**
Theme 1:
Theme 2:
Facilitator Assessment
A brief assessment of the successes and challenges of the process and discussion. Include suggestions or recommendations for future activities.

Transferring Data
Zoomerang is a HIPAA compliant survey tool the Center has chosen to ease the collection of data from the facilitated discussions. Using the Data Entry Template will best prepare you for entering your discussion data into the survey. The survey is organized to match the discussion guide, and the Data Entry Template is formatted exactly like the survey.

When you are ready to enter your data, click the appropriate link from your email to launch the survey. The first screen will include contact information for the Center, should you have any questions or difficulties as you move forward. Instructions at the top of each page will give you context for that section of the survey. You are required to enter data into each field before moving forward. If a question is not relevant, enter ‘N/A’ into the text.

Key things to keep in mind while preparing your summary:

- Fields are limited to 3000 characters, your will not see that it is cut off, but the text will not be transmitted in the results
- You are required to enter something in all fields, if the question is not relevant enter ‘N/A’
- If you need to make changes, you can move backwards in the survey, but you will lose any data entered further along
- Data will not be received by the Center until you reach the screen that says “Thank you for participating in this survey!”
- Each survey must be completed in one sitting, you CANNOT save and come back

Your data entry must be completed by February 8, 2012, or within one week of second discussion.

Facilitators should send hard copies and electronic files of discussion transcripts via courier service (either Fed Ex or UPS) within two weeks of the final group. All materials should be sent to:

Center for Evidence-based Policy
c/o Samantha Slaughter-Mason
345 SW Veterans Hospital Rd., SN-4N
Portland, OR 97239-2941
Appendix G: Voluntary Demographic Form (Facilitated Discussions)

Please complete the following information

Thank you for participating in today’s discussion group on patient involvement in health research. This form collects information on demographic characteristics of individuals participating in this group. This information will be used as part of the description of all the groups in the final report for this project. No personal identifying information will be collected with this form. The information collected in this form will not be linked to the information you provide as part of the discussion group.

Completion of this form is voluntary. You may skip any question you do not wish to answer.

Gender
- Female
- Male
- Transgender

Ethnicity
- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or Pacific Islander
- White
- Other

Age
- Under 20
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80-89
- Over 90

What is the highest level of education you have completed?
- Grade school
- Middle school or junior high
- Some high school
- High school
- Some college
- Associates degree
- Bachelors degree
- Masters degree
- Doctoral degree

What is your annual household income?
- Less than $10,000
- $10,000-$19,999
- $20,000-$29,999
- $30,000-$39,999
- $40,000-$49,999
- $50,000-$59,999
- $60,000-$69,999
- $70,000-$79,999
- $80,000-$89,999
- $90,000-$99,999
- $100,000-$149,999
- More than $150,000
- Prefer not to answer

Have you ever been in a health research study?
- Yes
- No

Have you ever helped to plan, or do, a health research study?
- Yes
- No
Appendix H: Voluntary Consent Form (Facilitated Discussions)

Oregon Health & Science University
Consent Form

IRB#: IRB00007914
Protocol Approval Date: December 19, 2011

OREGON HEALTH & SCIENCE UNIVERSITY
Consent Form

TITLE: Facilitated Discussions to Identify Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research

PRINCIPAL INVESTIGATOR: Pam Curtis, MA (503) 494-3264

CO-INVESTIGATORS: Valerie King, MD, MPH (503) 494-8694

SPONSOR: Patient Centered Outcomes Research Institute

This form contains important information about the study in which you are being invited to participate. Please read the form carefully, ask questions of the investigators or others who are obtaining your consent to participate in the study, and take time to think about your participation. You may want to discuss the study with your family or friends before agreeing to be in the study.

What is the purpose of this study?
The Center for Evidence-based Policy (the Center) has been awarded a short-term contract from the Patient Centered Outcomes Research Institute (PCORI). The institute was established by Congress through the 2010 Patient Protection and Affordable Care Act to help patients and their doctors or nurses make better healthcare decisions based on the best available science. This study is to being done to find out the best ways to include patients in the design of research focused on issues that matter most to patients. Information gathered from participants will guide future work in research study design and will explain how best to include patients in this work in a way that is most meaningful to patients.

What is required to participate in this study?
To qualify for this study, you must meet the following criteria:

1. Be 18 years of age or older.
**What can I expect as a study participant?**
If you agree to be in this study you will participate in a one-time group discussion on the design of health research. This session will be audio-recorded. You will be asked to share your thoughts and experiences with health research and health research design. We want to get your input on what you think is the best way to involve patients in research design. Your participation in this group discussion will take approximately 90 minutes.

If you have any questions regarding this study now or in the future, please contact Pam Curtis at (503) 494-3264 or Valerie King at (503) 494-8694.

**What effect will this study have on my care?**
Being in this study will not affect any care that you might receive at OHSU.

**How will my privacy be protected?**
We will protect your privacy in the following ways:

1. Personal information including your name and other protected information will not be used. Instead, we will identify you by code such a ‘Participant #1’.
2. Only study investigators will be able to access your information.
3. The information you provide on the registration form will be kept confidential and destroyed at the end of the project.
4. Audio-recordings of discussions will be destroyed after a summary report is written.
5. Comment will not be identified as coming from a particular participant as an individual.
6. All information will be stored in secure locations.

Research records may be viewed and copied by the OHSU Institutional Review Board and the Office for Human Research Protections.

**What are the possible risks of participating in this study?**
Some of the questions may seem personal or ask you to talk about personal experiences you have had in the past. You may refuse to answer any of the questions that you do not wish to answer.

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. If you share any personal information in this group discussion, the primary risk is a loss of confidentiality through discussion or through the unauthorized use of the audio-recordings prior to their destruction at the end of this project.

**What are the possible benefits of participating in the study?**
You may not personally benefit from participating in this study. However, you may contribute new information which may benefit the way patients help to design health research in the future. This may lead to better research questions and better answers to assist patients and their clinicians in making health care decisions. In this way, the work of this project may directly benefit you or others at some point in the future.
**Will it cost anything to participate?**
There is no cost to your for participating in the study. You will receive a gift card for your time.

**What if I am harmed or injured in this study?**
If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Pam Curtis at (503) 494-3264.

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have question on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

**What are my rights as a participant?**
If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of this form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU.

If the researchers publish the results of this research, they will do so in a way that does not identify you unless you allow this in writing.

You may be removed from the study if the investigator stops the study or if the sponsor stops the study.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course.
To participate in this study, you must read and sign this consent and authorization form. If you withdraw your authorization for us to use and disclose your information as described above, you will be withdrawn from the study. We will give you a copy of this signed form.

**SIGNATURES:**

Your signature below indicates that you have read this entire form and that you agree to be in this study.

__________________________       ______________________
Participant Signature        Date

____________________________
Print Witness Name

__________________________       ______________________
Witness Signature            Date
Appendix I: IRB Information Sheet (Facilitated Discussions)

OREGON HEALTH & SCIENCE UNIVERSITY
Center for Evidence-based Policy
Information Sheet

TITLE: Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcomes Research

PRINCIPAL INVESTIGATOR: Pam Curtis, MS
CO-INVESTIGATORS: Valerie King, MD, MPH
SPONSOR: Patient Centered Outcomes Research Institute

PURPOSE:
You have been invited to be in this research study because you have experience as a patient in the healthcare system in the U.S. The purpose of this study is to find out the best ways to include patients in the design of research focused on issues that matter most to patients. Information gathered from participants will guide future work in research study design and will explain how best to include patients in this work in a way that is most meaningful to patients. We plan to enroll about 100 participants in these facilitated discussions.

PROCEDURES:
You will participate in one 90-minute facilitated group discussion on patient involvement in health research. This session will be audio-recorded. You will be asked to share your thoughts about and experiences with health research.

RISKS AND DISCOMFORTS:
Some of the questions may seem personal, or ask you to talk about personal experiences you have had in the past. You may decline to answer any of the questions that you do not wish to answer.

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. If you share any personal information in this group discussion, the primary risk is a loss of confidentiality through discussion or through the unauthorized use of the audio recordings prior to their destruction at the end of this project.

BENEFITS:
There will be no direct benefit to you for participating in this study. However, by participating, you may help us to learn how to better involve patients in health care research. This may lead to better research questions and better answers that may assist patients and their doctors or nurses in making health care decisions.
**Alternatives:**
You may choose not to be part of this study; your decision will be anonymous.

**Confidentiality:**
No personal information will be included in the final analysis. Your name will not be collected, and any personal identifiers will be removed before data analysis. The information you provide on the demographic form will be kept confidential and destroyed at the end of the project. Audio-recordings of discussions will also be destroyed at the end of the project. Comments will not be identified as coming from specific individuals. Research records may be reviewed and copied by the OHSU Institutional Review Board and by the Office for Human Research Protections.

**Costs:**
There is no cost to your for participating in the study. You will receive a gift card for your time.

**Participation:**
If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator’s department, or your grade in any course.

This Information Sheet is yours to keep.

**Contact Information**
Please contact us with any questions or comments at:

Center for Evidence-based Policy  
Oregon Health & Science University  
3455 SW US Veterans Hospital Rd., SN-4N  
Portland, OR 97239-2941  
(503) 494-2182

The Patient-Centered Outcomes Research Institute solicits and receives input from the public about its work, as part of its commitment to transparency, credibility and access. PCORI encourages and values public input on all aspects of its work. You may provide feedback at any time by emailing info@pcori.org.

You may also visit the PCORI website at www.pcori.org and:
- Join the PCORI mailing list
- View public comments on previous topics
- Fill out an online form for general feedback to the program
Appendix J: PCORI/PCOR Information Sheet (Facilitated Discussions)

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment, and care options available, and the science that supports those options.

Research commissioned by PCORI will produce information patients and their health care providers can trust. Patients will play a major role in PCORI's work by telling PCORI what health care outcomes they value. PCORI will make sure the results of its research are provided to patients and clinicians in ways that are responsive to their needs and interests and easy to understand. PCORI is an information resource, not a care provider. In releasing its research findings, PCORI will ensure that its research is not construed as mandates for practice guidelines or coverage recommendations.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a series of formal public comment periods to increase awareness of its work and obtain public input and feedback prior to adoption of priorities, agendas, methodological standards, peer review processes or dissemination strategies.

PCORI was established by the US Congress through the 2010 Patient Protection and Affordable Care Act, but is by law an independent, non-profit organization. PCORI is governed by a 21 member Board of Governors.

Patient-centered outcomes research is designed to inform health care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options for different patients. The evidence is generated from studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care. This research recognizes that the patients voice should be heard in the health care decision making process. PCORI's research will be responsive to the preferences, values, and experiences of patients in making health care decisions and the impact diseases and conditions can have on daily life.

The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed health care decisions — and improves health care delivery and outcomes — by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community.
Patient-Centered Outcomes Research (PCOR)

Individuals (patients, physicians, and policymakers) and groups (insurance companies, Medicaid, and hospitals) are making important decisions about health care treatments and interventions every day, whether or not they have research information. Providing these decision-makers with the best available scientific evidence supports their ability to make the best possible health care decisions. This is the focus of patient centered outcomes research (PCOR).

PCOR is research that is informed by the perspectives, interests and values of patients throughout the research process, from the selection of research questions to the dissemination of research results. This research also includes bridging information gaps about what works and what does not work in health care services and by identifying important areas for future research. Patient-centered outcomes research is intended to be practically relevant. Its real-world impact on patients is known and included in decisions about prevention, diagnosis and treatment.

Patient Centered Outcomes Research (PCOR) helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions, such as:

- “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
- “What are my options and what are the benefits and harms of those options?”
- “What can I do to improve the outcomes that are most important to me?”
- “How can the health care system improve my chances of achieving the outcomes I prefer?”

To answer these questions, patient centered outcomes research:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.
Appendix K: Ground Rules Poster (Facilitated Discussions)

Objectives
- To explore and record ideas of how best to involve patients in research
- To explore and record ideas of ineffective approaches to patient involvement
- To determine the best way to find and recruit patients

There are no right, or wrong answers

Share your views, even if they are different from what other people are saying

Be respectful of your fellow participants

Speak one at a time — let people finish what they are saying before you begin to speak

Respect each other’s privacy

Do not talk with your neighbor while someone else is speaking to the group

Speak only for yourself and let others do the same

Please do not repeat personal information shared by others outside of this room
Appendix L: Example Research Process Poster (Facilitated Discussions)

Example Research Process

- **Topic Identification**
  - What topics (treatments, tests, drugs, etc.) need more research?

- **Topic Refinement**
  - What questions need to be answered? What outcomes are important? What information do you need to make a decision?

- **Research**
  - How should the research be done? What does the research need to include?

- **Translation**
  - What does the research say? How does it help decision-making?

- **Dissemination**
  - Who needs the information? How can you get it to them?
What does being involved in health research look like?

- Submitting an **online nomination** for a study condition that has impacted your life
- Being part of a **focus group** to share your experiences with a certain treatment
- **Giving testimony** at a public hearing to share the results of a study you were involved in
- **Giving input on the language and methods** to explain study results to other patients
- Using your experience to **help researchers define what questions are asked** in a research study
- **Suggesting locations** in your community for hosting community-based interventions
- Participating in **facilitated discussions** about health topics
Appendix N: Demographic Characteristics of Facilitated Discussion Participants

Gender

- Transgender: 1%
- Male: 35%
- Female: 64%

Ethnicity

- Other
- White/Caucasian: 80%
- Native Hawaiian or Pacific Islander
- Hispanic/Latino: 20%
- Black/African American
- Asian
- American Indian or Alaska Native