



**Improving health outcomes by putting patients first**



## **VISION**

Patients and the public have the information they need to make decisions that reflect their desired health outcomes.

## **MISSION**

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.

"Members of the public, patients and consumers, can be a force that can make these reforms succeed if they are utilized, and the time is now to begin that communication..."

—Florence Fee, President, No Health Without Mental Health



IMPROVING  
HEALTH  
OUTCOMES  
BY PUTTING  
PATIENTS FIRST



"I believe that our accountability is to patients. Ultimately, we're going to be listening to a lot of stakeholders, but our true north is going to be patients—patients and their caregivers, those individuals who are working together grappling with these decisions, for whom the consequence of the decision...means everything... In this conception, I think maybe we have a chance to turn the world upside down just a bit."

—PCORI Board of Governors Member Harlan Krumholz, M.D.



Eugene Washington and Steven Lipstein

**“Patients, clinicians, and other stakeholders want and need research that directly addresses the health care decisions they face, and that reflects their values, preferences, and goals. That’s the kind of research we want to fund and sustain.”**

**W**hen the Patient-Centered Outcomes Research Institute (PCORI) was created, two years ago, it had a substantial statutory mandate—improve clinical decision-making by supporting research that carefully considers the unanswered questions and concerns of stakeholders, with patients and their caregivers at the center of that process.

Over the past year, we’re pleased to say, PCORI has made substantial progress toward this ambitious goal, which envisions essential changes in the way traditional medical research is conducted and more effective and efficient mechanisms to ensure that the results of that research are disseminated to stakeholders and incorporated into practice.

Guided by our legal obligations, we started with the basics—creating a workable definition of “patient-centered outcomes research” and drafting a set of national priorities and an initial research agenda that will serve as a road map for our work. We also moved to establish research methods that support the engagement and meaningful inclusion of patients and other stakeholders at every step of the process, from the selection of study questions to the dissemination of results. We also have taken a series of initial steps toward funding research projects, with many more scheduled to be funded in coming months.

Our success over the past year is the result of many important factors, but perhaps none more so than the commitment and collaborative spirit of our 21-member, multi-stakeholder Board of Governors. We represent consumers, patients, caregivers, clinicians, hospitals and health systems, researchers, payers, insurers, industry, and policymakers. And we have found a remarkable degree of agreement about what matters most as we pursue our goal of laying the foundation for a unique research enterprise.

Our work has expanded rapidly with the addition of Joe Selby, M.D., M.P.H., our inaugural Executive Director, and a full-time permanent staff. And, as a learning organization, we regularly solicit and use the input from a range of stakeholders to guide our efforts. The public plays a critical role in helping define patient-centered outcomes research, providing early feedback on our draft National Priorities for Research and Research Agenda, and serving as merit reviewers for our Pilot Projects awards program. As we continue to bring on expert staff and build organizational capacity, the volume and sophistication of our engagement and input opportunities will grow.

Patients, clinicians, and other stakeholders want and need research that directly addresses the health care decisions they face, and that reflects their values, preferences, and goals. That’s the kind of research we want to fund and sustain. We’re confident that, building on the progress we’ve made in the past year, with a foundation of significant and ongoing engagement with the many communities we serve, we are well on our way.

Thank you for your interest in and support of PCORI. We look forward to continue working with you to ensure that patients and the public have better information they can use to make decisions that reflect their desired health outcomes.

**A. Eugene Washington, M.D.**

*Vice Chancellor, UCLA Health Sciences, and  
Dean of the David Geffen School of Medicine, UCLA  
Chair, PCORI Board of Governors*

**Steven Lipstein, M.H.A.**

*President and Chief Executive Officer,  
BJC HealthCare, St. Louis, Mo.  
Vice Chair, PCORI Board of Governors*

**“We fully expect that, with PCORI’s work, this patient-centered approach can become a new standard for clinical research. We’re confident that the result will be better information, better decisions, better care, better outcomes, and better health for all of us.”**



**Joe Selby and Anne Beal**

**A**s a family physician and a pediatrician, we’ve cared for thousands of patients over the years. We’ve spent countless hours doing our best to help our patients and their families find their way through complex, difficult, and sometimes frightening health care decisions. And one of the biggest lessons we’ve drawn from these experiences is that, when clinicians and patients have the right information they need to make decisions, and do so as fully engaged partners, everyone benefits.

Sometimes, we’re fortunate to see this happen, not just in our own practices but in our personal lives. For one of us, it involved the case of an elderly parent who, although struggling with a serious illness that required making some tough choices, felt that his physician had shared with him information about treatment options that he trusted, and that took account of his personal priorities and concerns.

Unfortunately, this isn’t as common a situation as we might hope. We know physicians don’t always have all of the data we’d like in order to help patients choose between various clinical options, or the information we do have doesn’t indicate which option might best address a patient’s particular needs. For example, what if a patient’s biggest concern is pain, or physical or mental debilitation? What if the main concern is maintaining the ability to pursue familiar day-to-day activities, or the ability to take care of loved ones, like one’s own children?

Not only do we have firsthand experience with these challenges as clinicians, but we’ve also faced them from the other side of the exam table, when one of us or one of our family members has needed care. Even

as doctors, when in the role of patient or caregiver, we’ve sometimes felt far more left out of the clinical decision-making process than we would have wanted or expected, and have lacked the information most relevant to our particular situation.

Addressing these concerns starts with recasting the nature of the research upon which we base the options we present to our patients. It’s our job, and that of our colleagues at PCORI, to do just that, working to reshape approaches to research so that patients and other critical stakeholders are fully vested partners in the quest for new knowledge that will benefit them directly. We can do so not just by carefully and fully listening to the communities we serve but by taking their concerns to heart and incorporating them into the work we do in ways that have lasting influence.

This commitment to engaging patients in research is in our DNA, from developing the questions to be explored in a particular study to conducting the research itself, analyzing the results, and making that information widely available in ways that can be readily understood and used by patients and those who care for them.

We fully expect that, with PCORI’s work, this patient-centered approach can become a new standard for clinical research. We’re confident that the result will be better information, better decisions, better care, better outcomes, and better health for all of us.

**Joe V. Selby, M.D., M.P.H.**

*Executive Director*

**Anne C. Beal, M.D., M.P.H.**

*Chief Operating Officer*



## PCORI: The path to a new model for research

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by the Patient Protection and Affordable Care Act (PPACA) of 2010 to conduct research to provide the best available evidence to help patients and those who care for them make better-informed health care decisions.

Research undertaken and supported by PCORI is intended to develop information that will give patients and those who care for them a better understanding of the prevention, treatment, and care options available and the science that supports those choices, guided by nine criteria outlined by law.

PCORI is unique both in our mission—to focus not just on comparative clinical effectiveness research but on patient-centered outcomes research—and in how we seek to fulfill it, namely by advancing research that is guided by patients, caregivers, and other health care stakeholders.

This report documents PCORI's activities over a 14-month period, from January 1, 2011, through the close of the public comment period on our draft National Priorities for Research and initial Research Agenda on March 15, 2012. During that

time, guided by our commitment to meeting both the letter and the spirit of our statutory obligations, we made substantial progress in establishing PCORI as a new national research entity committed to engaging patients and a broad range of other stakeholders in our work. That work includes:

- Laying the groundwork for a new national health research institute, including establishing governance processes, hiring staff, and initiating work on a strategic plan.
- Building a framework for soliciting and incorporating patient and other stakeholder input into activities and initiatives on an ongoing basis.
- Defining Patient-Centered Outcomes Research (PCOR).
- Creating a Pilot Projects Program, an effort to help refine the methods available for involving patients and other stakeholders in the specific tasks that would guide PCORI's work.
- Developing Draft National Priorities for Research and an Initial Research Agenda, the road map for the work we plan to do.
- Drafting an initial Methodology Report, a detailed reference for the research community on how to rigorously and sustainably conduct PCOR.

### The Nine Statutory Criteria That Drive PCORI's Work

Impact on Health of Individuals and Populations	Addresses Current Gaps in Knowledge/Variation in Care	Patient-Centeredness
Improvability Through Research	Impact on Health Care System Performance	Rigorous Research Methods
Inclusiveness of Different Populations	Potential to Influence Decision-Making	Efficient Use of Research Resources

PCORI has worked throughout the past 14 months to build a major national health research institute from the ground up, utilizing a rigorous stakeholder-driven process that emphasizes long-term patient engagement. These efforts have been driven by our 21-member, multi-stakeholder Board of Governors, while a 17-member Methodology Committee has worked to develop and advance the science and methodologies of comparative clinical effectiveness research (CER) and PCOR. Members of the Methodology Committee are experts in their fields, which include, but are

**“In the past 10 years, I’ve seen increasing awareness of the value of patients’ input to policy and regulatory decisions, what I see as a major paradigm shift from expert-dominated medical decision-making, where the patient’s role is that of a passive recipient of treatment, to truly patient-centered health care...”**

—Perry D. Cohen, Ph.D., Founder and Director, Parkinson Pipeline Project, and patient

not limited to, health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. Our Board and Methodology Committee have also established a number of other committees to provide focus for key areas of our work.

When PCORI’s Board of Governors was empaneled on September 23, 2010, by the U.S. Comptroller General, we had our establishing legislation to guide our work and a budget to support our activities, but no administrative or operational infrastructure. The Board immediately went to work strengthening the institute’s governance, establishing an initial organizational framework, hiring an executive director, developing a consensus on our mission, delineating processes for proposing national research priorities and a research agenda, and getting to work in producing our first Methodology Report. These efforts have been guided by the mission statement that the Board adopted in July 2011.

This involvement of patients and other health care system stakeholders in all phases of research is not only a distinguishing characteristic of our mission—it is also essential to gaining broad acceptance of the evidence-based information that PCORI-supported research will produce. Indeed, the concept of patient and stakeholder engagement is a primary pillar upon which we are building a path to lasting impact in patient-centered outcomes research, the others being rigorous methods, research, dissemination, and infrastructure development.

Our fundamental commitment to transparency, credibility, and access begins with the work of the Board, which has held open meetings bimonthly in cities around the country, with public comment periods, live webcasts allowing any interested party to participate, and, on a number of occasions, associated community engagement activities. Past meeting agendas and materials are archived on the PCORI Web site <http://www.pcori.org/meetings-events>.

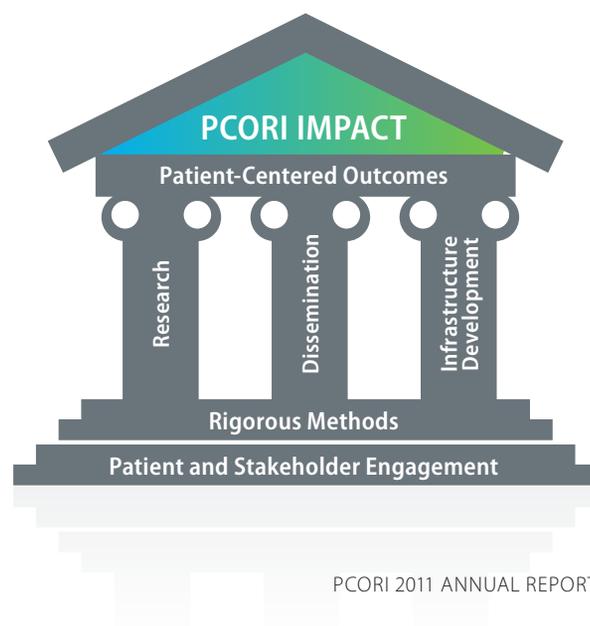
PCORI established a foundation for a permanent staff to carry out the institute’s work under the Board’s direction

with the appointment of our first Executive Director, Joe V. Selby, M.D., M.P.H., who began his duties in July 2011. Dr. Selby quickly went to work building a team of research, engagement, and administrative professionals dedicated to advancing PCORI’s patient-centered mission, starting with Chief Operating Officer Anne Beal, M.D., M.P.H., who came on board in November 2011. Additional professional staff soon followed.

With the staff’s expansion, the Board began the transition from a robust operational role to a more traditional governance role. The transition was guided in part by the Board’s engaging with staff in an iterative process to develop a strategic plan for the institute. The Board is to consider a draft of the plan for adoption in late May.

Reinforced by the Board’s work and the growing contributions of staff, we entered 2012 poised to support a growing effort to actively incorporate the voices of patients and other stakeholders in the process of producing, disseminating, and using trusted, evidence-based information that will enhance clinical decision-making and ultimately lead to better health for all.

### PCORI’s Foundational Pillars





## An evolving framework for patient and stakeholder engagement

**W**e have adopted a wide range of approaches to making real our commitment to transparency, credibility, and open access in all aspects of our operations. Our goal is to ensure that patients, caregivers, clinicians, and other stakeholders not only trust the research we support and the information we produce, but will be motivated to participate substantively in our work, from the way the studies we fund are designed and implemented to how their results are disseminated and, we hope, widely used to improve medical practice.

This approach starts at the top. Our open bimonthly Board meetings have featured a number of community engagement activities, such as presentations and roundtable discussions with patients and patient advocates, clinicians, researchers, and industry representatives, to explore perceptions of the meaning of “patient-centered outcomes research,” develop a deeper understanding of the kinds of outcomes valued by patients, and learn where patients now turn for health information. The Board has kept a particular focus on ensuring that the interests of patients, caregivers, clinicians, and others in underserved communities are well represented in our work.

We have regularly and frequently engaged patients, caregivers, clinicians, and others through a series of focus groups on various aspects of our work, particularly our development of the PCOR definition and our draft National Priorities for Research and Research Agenda. Public comment periods and associated outreach efforts are required as part of the process of finalizing our priorities and agenda and another critical resource, our first Methodology Report. Patients will be on the review panels that will rank the primary research funding applications we receive—applications that will require researchers to outline how they plan to engage patients in study design and in disseminating their results to stakeholders for whom the research is relevant.

We also began to build the structures needed to ensure that the results of the research we support not only are disseminated widely to the stakeholders with whom we engage but are used by those audiences consistently and effectively. Direction for this core function, outlined in our establishing legislation, was set by the Board’s Communications, Outreach and Engagement Committee and the Methodology Committee’s Work Group on Dissemination. A Dissemination Work Group, comprised

### PCORI Timeline





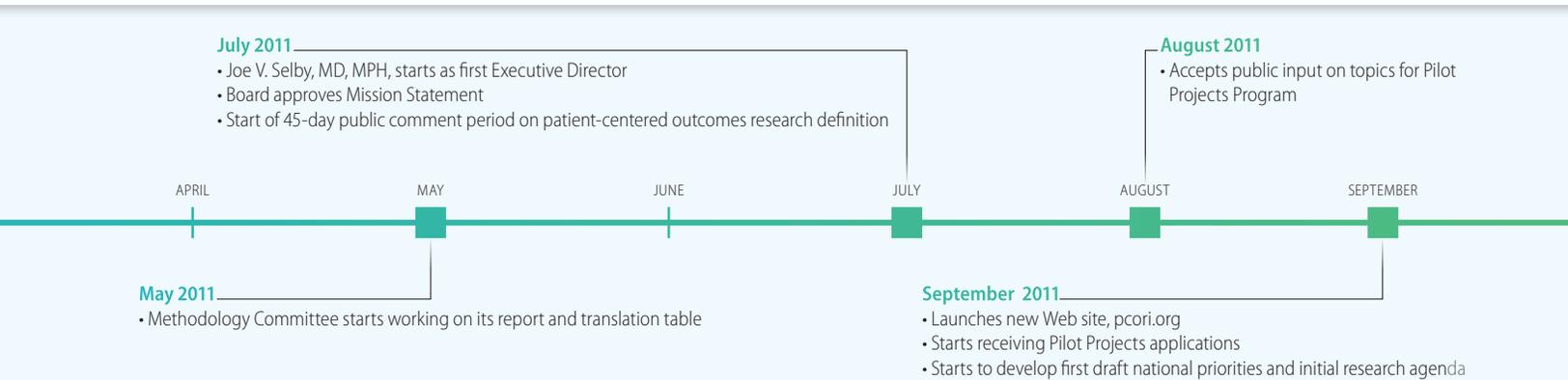
of PCORI Board members and staff from the Agency for Healthcare Research and Quality (AHRQ), PCORI's official dissemination partner by statute, is working to build a framework for PCORI dissemination. The Work Group's goal is to ensure complementary dissemination work that avoids duplication and facilitates success, which for PCORI equals a positive impact on practice and patient outcomes.

The Board and members of the Methodology Committee met with patients, caregivers, patient advocates, clinicians, nurses, researchers, payers, and others from the health care community in small roundtable discussions at the March and May 2011 Board meetings in St. Louis and New York, respectively. In Washington, D.C., in July, the Board and Methodology Committee fanned out in small teams across the capital area to meet with 43 organizations representing patient advocacy groups, nursing disciplines, medical specialties, medical technology and research fields, and payers and policymakers. In Seattle, in September, the Board spent an evening with representatives from health service organizations and health care providers

(including the Indian Health Service), as well as comparative effectiveness researchers engaged in collaborations across the Pacific Northwest. In New Orleans, in November, the Board heard from an invited panel of regional health care researchers and clinicians, and visited two community clinics to hear from patients and their caregivers in underserved communities. In Jacksonville, Florida, in January 2012, PCORI heard from a panel of regional patient, clinical care, research, and payer representatives, as well as individual patients.

**“As one of our patients so eloquently stated, an outcome is where I end up. That’s what they care about...”**

—Barbara Summers, PhD, RN; VP and Chief Nursing Officer, University of Texas MD Anderson Cancer Center





Specific milestones achieved during the year included relaunching [www.pcori.org](http://www.pcori.org), starting to build out a robust e-mail communications system, and establishing plans for ongoing convening initiatives. We also put in place a speakers' bureau that arranged Board and staff talks at dozens of national and local meetings and professional conferences with patients, clinicians, caregivers, researchers, industry representatives, health care purchasers, and policymakers. The goal of all of these activities is to bring to as many interested audiences as possible our message of inclusion of all voices in the conversation about providing better information to patients and the people who care for them.

These and other initiatives, described in greater detail in the table on the right, are just the beginning of our efforts to serve patients and other stakeholders across the nation. The goal is to establish and maintain an increasingly sophisticated conversation about how we can most effectively support research that will lead to better-informed health care decision-making. We want stakeholders not only to learn about our activities but to establish reliable and accessible mechanisms for them to provide us with the feedback we need to help shape our work in the longer term.

### Engagement Activities at Board Meetings

(March 2011–January 2012)

Date	Location	Stakeholders
March 2011	St. Louis, MO	Patients, caregivers, patient advocates, clinicians, nurses, researchers, payers, and others
May 2011	New York, NY	Patients, caregivers, patient advocates, clinicians, nurses, researchers, payers, and others
July 2011	Washington, DC	Patients, caregivers, patient advocates, clinicians, nurses, researchers, payers, and others
September 2011	Seattle, WA	Clinicians, researchers, and the Indian Health Service
November 2011	New Orleans, LA	Researchers, clinicians, patients, and caregivers at community health clinics
January 2012	Jacksonville, FL	Patients, researchers, and payers

### PCORI Timeline

#### November 2011

- Anne Beal, MD, MPH, starts as Chief Operating Officer
- Conducts patient and caregiver focus groups on definition of patient-centered outcomes research
- Creates Standing Committee on Conflicts of Interest
- Starts to conduct patient and caregiver focus groups to support priorities development (through December)

#### March 2012

- Begins analysis of public comment on draft National Priorities and Research Agenda



#### October 2011

- Awards RFP contracts to support Methodology Report development
- Establishes Dissemination Working Group
- Receives 349 stakeholder and 600 scientist reviewer applications for grants
- Conducts webinars (850 registrants) on Pilot Projects Program

#### January 2012

- Starts to receive input on Draft Translation Table Framework
- Awards contracts to review guidance documents for selecting PCOR methods
- Releases draft National Priorities and initial Research Agenda for public comment

## A period of major milestones and accomplishments

PCORI's achievements over the past 14 months have laid a solid foundation for its future work, including issuing the first in a continuing series of calls for applications for research funding. Each accomplishment, outlined in detail in the following pages, has been a critical step along that path toward supporting research designed to make patients and caregivers meaningful partners in the research process.

### Defining Patient-Centered Outcomes Research

Despite Congress' choice of PCORI's name, there was no consensus in the field on a formal definition of "patient-centered outcomes research," although the term was in use. One of PCORI's foundational tasks, therefore, was to clearly define the term, as an initial step in honing our focus and scope of work, including how PCOR relates to comparative effectiveness research.

In March 2011, the Methodology Committee began an extensive, transparent process for defining PCOR. The committee held a series of discussions that generated several draft definitions, which were presented and considered at the public Board meeting on March 8. Feedback was incorporated into eight subsequent hours of Committee deliberation to reach consensus on the definition's specific language. The Committee approved a draft definition in April and presented it to the Board for approval at its May meeting.

The draft definition of PCOR was posted for a 45-day comment period. Nearly 120 organizations and 450 individuals responded, representing virtually every perspective within the health care community. Comments were analyzed and a report published summarizing respondents' reactions and suggestions.

We sought further input by conducting six focus groups aimed at determining whether the draft definition resonated with patients, caregivers, and the general public. About 60 people participated in three metropolitan areas—Chicago, Richmond, and Phoenix. To ensure a diversity of perspectives, one group was conducted in Spanish with Latino patients and caregivers and one exclusively included African-American patients and caregivers.

Based on feedback obtained through these forums, the Committee made several recommendations to the Board for further revising the draft, summarizing its proposed changes in an accompanying analysis. The Board adopted the revised definition at its March 2012 meeting.

Adoption of the PCOR definition was not the end of the process, however. We consider it a "living" document, subject to ongoing revision and refinement through a rigorous and standardized process, as this field of research grows and the needs of patients and other stakeholders continue to evolve and be identified. We believe that this emphasis on soliciting feedback and incorporating it into our work is a core value, and that committing to doing so over time is proof of our vision for a new and more inclusive model of research. It also is emblematic of our dedication to being a "learning" organization.

### Establishing PCORI's First National Priorities for Research and Initial Research Agenda



## Pilot Projects Program

We developed our Pilot Projects program as part of our effort to refine the methods available for involving patients and other stakeholders in the process of establishing national priorities for research, informing the development of a research agenda, and conducting and advancing the dissemination and use of PCOR.

Public input was a critical component in shaping the program. Originally proposing eight areas of interest, we sought stakeholder comment on the Pilot Projects program over a 30-day period, receiving 160 submissions through our Web site, e-mail, and regular mail. The proposed focus areas were modified in response and, in September, we issued a request for applications promoting observational methodologies, systematic reviews, mixed methods and qualitative methodologies, simulations, small pragmatic pilot trials, and survey methods. Specifically, we sought proposals on:

- Patient and stakeholder engagement in identifying gaps in knowledge and research needs
- Patient and stakeholder participation in research priority setting
- Development of patient-centered research methods
- Patient-oriented outcomes instruments
- Incorporation of patients' perspectives in research related to studying behavior change
- Patient-provider communication and other decision-making strategies
- Collaboration with stakeholders in building research teams
- Translation of research findings into clinical practice

The response from the research community was extremely robust, suggesting a readiness to embrace a larger shift toward the institute's patient-centered focus. We received nearly 1,400 letters of intent, followed by 842 applications

that addressed a broad range of questions about methods for engaging patients in the research and dissemination process. To assist applicants, we held three webinars explaining the application and funding process, drawing 850 registrants and answering 1,400 applicant questions.

Seeking broad stakeholder engagement was critical to the next stage in the Pilot Projects process as well, as we issued a call for reviewers to assess the funding applications submitted. We received nearly 350 reviewer applications from stakeholders, nearly half of those from patients, patient advocates, and caregivers. Six hundred scientists also volunteered to serve as reviewers.

Merit reviews, conducted by interdisciplinary teams of 20 individuals each, took place in February. A Selection Committee, made up of Board members, reviewed the resulting merit scores and prepared a recommended slate of projects for funding consideration, taking all areas of interest into account in an effort to support a diverse set of projects. The full Board is to consider the recommendations in late April with the goal of making funding decisions and announcing awards by May.

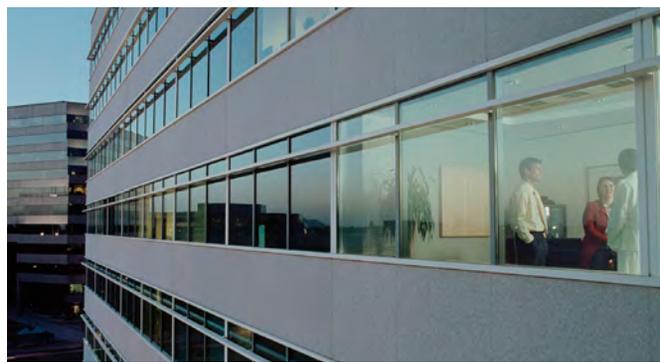
## Developing National Priorities for Research

We were charged with developing national priorities for research as one of the critical tasks to be completed before we could start funding primary research. The process of drafting these research road maps began in August 2011 under the direction of the Board's Program Development Committee, which conducted an extensive review of nine previous national efforts to establish priorities for comparative effectiveness research. Particular attention was given to the degree to which each of these prioritization efforts involved substantive stakeholder engagement and public input.

The review identified 10 common themes that consistently appeared as priority areas for research. These were measured against our working definition of patient-centered outcomes research to determine five cross-cutting areas that would become our research priorities.

## PCORI's Draft National Priorities for Research





## Establishing a Research Agenda

Using the draft priorities as a foundation, the Committee developed an initial research agenda by applying to the priorities the research criteria stipulated in our establishing legislation (see page 4). Each of the research agenda's resulting areas of focus represents a line of research inquiry that addresses unmet needs and gaps in information available to patients, their caregivers, clinicians, and other stakeholders for making the best possible, personalized decisions across a wide range of conditions and treatments.

## Reflections on the Process of Establishing Priorities and a Research Agenda

The draft priorities and research agenda are intentionally broad, and are not limited to specific conditions or therapeutic interventions. We took that approach because there are many important questions to be answered from a patient-centered outcomes research perspective. Focusing on a narrow set of conditions at the start of our funding process could have excluded many patients at a critical, early stage in our work. We expect to see greater specificity about conditions in the research we fund as we continue to solicit and weigh stakeholder input—a process we are committed to pursuing in a transparent, systematic way so that there is a clear path to reaching a more targeted set of research questions.

We began incorporating patient and other stakeholder perspectives early in the National Priorities and Research Agenda process, tapping into the experience of Board members and holding a series of meetings with organizations representing patients as well as other stakeholders to help inform the drafts developed for public comment. In

addition, patient and caregiver focus groups were conducted in November and December 2011 to provide early input on developing the priorities. Our executive staff and Board members also discussed the process with numerous stakeholder organizations, including patient representatives.

We released our draft National Priorities for Research and Research Agenda in January 2012 for a 53-day public comment period, soliciting feedback through a Web-based survey tool, e-mail and regular mail, clinician focus groups, print and online advertisements placed in a wide range of consumer and professional media, and our national "Patient and Stakeholder Dialogue" event and associated webcast that drew a total of nearly 850 participants. These outreach efforts yielded nearly 500 comments from individuals and organizations by the close of the comment period.

After completing a careful review and analysis of the comments, the Board will consider for adoption a revised version of the draft priorities and agenda during a public conference call/webinar in late April, followed by the issuance of initial funding announcements in May. A report summarizing the feedback received and how it was incorporated into recommended changes in the draft priorities and agenda will be published on [www.pcori.org](http://www.pcori.org) along with the revised document.

As with the PCOR definition, our National Priorities for Research and Research Agenda are considered living documents that will evolve as we gain greater understanding of the gaps in patient-centered outcomes research. We will continue to seek and incorporate the comments of patients, their caregivers, and all stakeholders to ensure that this guiding document remains focused on and relevant to the needs and concerns they identify.



**“We’d like to involve patients in order to see improved outcomes—in terms of the results of studies being outcomes patients care about. We’d also like to establish a base of trust. If researchers partner with patient communities, this will help bridge the gap between what we’d like to achieve and getting there..”**

—Methodology Committee workshop participant

## Developing PCORI’s First Methodology Report

Just as PCORI is directed by statute to adopt National Priorities for Research and an initial Research Agenda as a road map for funding, so must our efforts be guided by the work of our Methodology Committee, charged with developing and periodically updating methodological standards for CER and PCOR. The Committee’s goal is to establish a rigorously developed foundation for continuing work in the field—a framework that may be used by researchers across discrete professional sectors. The first product of this effort will be our draft Methodology Report, a resource that we and the Committee hope to see refined, improved, and widely utilized over time through broad stakeholder input and collaboration.

PCORI’s Methodology Committee is charged with developing standards to:

- Provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research, and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of the research.
- Be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the institute, as appropriate.
- Include input from relevant experts, stakeholders, and decision-makers and shall provide opportunities for public comment.
- Include methods by which patient subpopulations can be accounted for and evaluated in different types of research.
- Build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of CER (determined as of the date of enactment of the PPACA).

The Committee undertook a full slate of activities during 2011 that laid the groundwork to meet this goal and to create a required translation table, a tool designed to provide guidance in determining which research methods should be used to address different research questions. Four working groups—on patient-centeredness, research priorities, research methods, and report assimilation—were established to guide the Committee’s work.

The Committee issued a request for information (RFI) to solicit input from methodologists on the translation table. The RFI resulted in the submission of 24 responses, many from leading organizations and institutions in the field. The Committee developed requests for proposals (RFPs) to (1) review guidance on selected research methods; (2) review and synthesize evidence for eliciting the patient’s perspective in patient-centered outcomes research (through literature review and expert stakeholder interviews); and (3) develop white papers on methods for setting priorities in research. The Committee oversaw a rigorous proposal review process that resulted in issuing 15 awards to major research organizations from across the country during 2011 and one more in early 2012. These projects are listed on page 17.

In conjunction with the March Board meeting, two of the Committee’s working groups held a series of expert workshops to review the results of these projects as part of the process of developing the first set of standards for the full Committee report. A subgroup of the Committee also continued work on the translation table.

The Patient Centeredness Work Group workshop involved 14 researchers from the five research teams contracted for the group, along with eight outside invitees—experts in patient-centered outcomes research, health consumer research, and patient-reported outcomes measurement, as well as a patient representative. Participants reviewed project findings for stakeholder and expert input on engaging patients in PCOR along with findings on standards for use of patient-reported outcome measures in PCOR, and discussed ways in which the findings could inform methodological standards for PCOR.



The Research Priorities Work Group workshop was held with researchers from five contracted research teams. The purpose of this workshop was to gather perspectives on how selected methods might be used by PCORI to inform the process of establishing research priorities. The research areas addressed were approaches to topic generation, gap analysis, value of information analysis (two projects), and peer review for research prioritization. Two outside experts served as facilitators.

As of the date of this report, the Committee was in the process of using the work resulting from these projects to develop the first set of standards that will appear in the first Methodology Report, to be submitted to the Board of Governors as required by statute on May 10, 2012, and published for public comment following Board acceptance.

### **2011 Requests for Proposals (RFPs) to Support Methodology Report Development**

- Review of Guidance Documents for Selected Methods in Patient-Centered Outcomes Research
- Review and Synthesis of Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcomes Research (Literature Review)
- Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcomes Research (Interviews)
- Methods for Setting Priorities in Research (White Papers)

### **Research Funding Opportunities**

We make a variety of external funding opportunities available throughout the course of our work, issuing RFPs and awarding contracts through a competitive process.

Calls for proposals are published on our Web site in the Funding Opportunities section, sent to our opt-in e-mail list, and promoted through a number of other outreach mechanisms, including through relationships with stakeholders and other partners.

Proposals submitted after an RFP is finalized will be reviewed in a process that can incorporate scientific review by the Methodology Committee and Board members, when appropriate. We pay careful attention to exclusion of reviewers with a conflict of interest; all final decisions are made by the Executive Director. All awards upon approval and the results of all funded projects, upon completion, will be published on [www.pcori.org](http://www.pcori.org).

We used this award process in 2011 to support the work of our Methodology Committee by issuing 15 contracts in response to RFPs across three areas to support the development of our first Methodology Report, as described above; two additional contracts were issued in early 2012.

We also funded, through an RFP, analysis of the public input received on the working definition of "patient-centered outcomes research" and of the feedback received from patient and caregiver focus groups designed to assess their understanding of the definition. The results of this research were used to revise the definition and ensure that patient and caregiver perspectives are reflected in its language and intent.

For a complete listing of these contracts, see page 17.

## A look ahead: PCORI's plans for 2012

The past year was one of critical structural growth for PCORI, and 2012 promises to be a year of rapid progress toward building a dynamic research portfolio—one with patients' needs and values at its core and a focus on building a sustainable patient-centered research enterprise as its goal.

Through a continued focus on enhancing patient and stakeholder engagement, we will finalize our National Priorities for Research and initial Research Agenda, hone our methodological standards for research, approve 40 or more Pilot Projects awards, and issue our first call for broad primary research funding proposals. As the year progresses, we will issue targeted research funding announcements. By year's end, we plan to commit approximately \$120 million in primary research support and then start preparing for additional funding cycles into 2013 and beyond.

As we move through our primary research funding cycles and continue to grow as an organization, we will be guided by the same mission, vision, and operating principles described above. Three areas of focus are worth particular mention.

### 1. The Primacy of Patient and Stakeholder Engagement

This will remain our guiding principle as we build our capacity as a scientific enterprise that contributes to reshaping how research is conducted. Our staff will be guided by strategic and operational plans designed to address evolving stakeholder needs, and will continue to solicit input to help shape the institute's initiatives.

We plan a wide array of multidirectional engagement initiatives involving patients, caregivers, clinicians, and other critical audiences. They will include live and virtual forums, focus groups, workshops, and meetings with groups of

patients, caregivers, clinicians, payers, and others. We are especially committed to doing this work in communities that experience health disparities across the U.S., to understand and respond to the needs of those patients and stakeholders often overlooked by the research enterprise.

We also plan to establish advisory groups of patients, caregivers and other stakeholders to help shape the direction of the organization's work in such areas as research networks, dissemination, clinical trials and observational studies, electronic health records, and building long-term PCOR capacity. Driving home the value we place on engagement will be the inclusion of criteria requiring a robust, detailed engagement plan as part of all funding proposals.

### 2. Communications and Dissemination as Critical Constructs

Just as we take our commitment to stakeholder engagement seriously, so too do we realize that conducting research—even in ways that more fully involve those stakeholders—is not enough to meet our obligations. Equally important is our ability to develop and effectively deploy mechanisms that will communicate and disseminate those research results to those who need them, in formats that are accessible, understandable, and relevant. Perhaps even more critical is recognizing that even sophisticated communication and dissemination initiatives are still only part of the picture. The real goal is sustained uptake and use of the research results we support in ways that measurably improve practice and, ultimately, patient outcomes.

Our task here is clearly outlined in our establishing legislation, which requires the Office of Communications and Knowledge Transfer of the Agency for Healthcare Research and Quality (AHRQ), in consultation with the National Institutes of Health (NIH), to "broadly disseminate" the research findings we

### PCORI Timeline

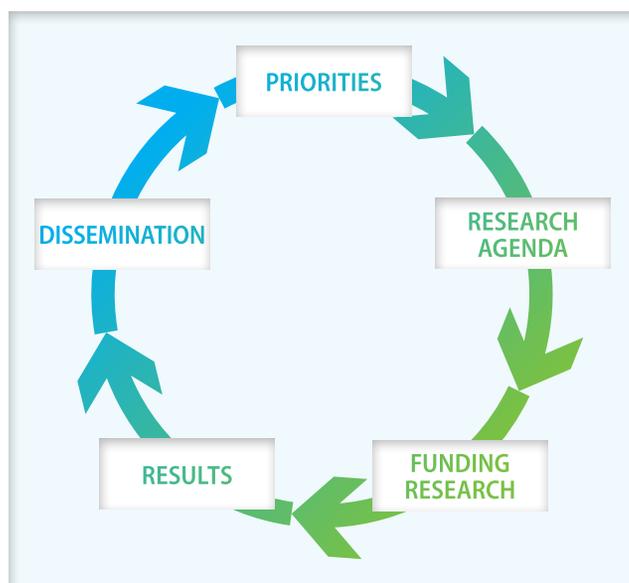


publish to a range of stakeholder audiences. Doing so effectively will require a robust PCORI-specific communications and dissemination framework developed in close collaboration with AHRQ, which has a rich history of expertise in this field. Effective implementation not only demands that that collaboration continue and grow, but will necessitate the establishment of a broad network of partnerships with organizations and institutions across the spectrum of stakeholder sectors, so that the effect of our outreach efforts is steadily amplified and ripples outward through professional and other stakeholder communities.

PCORI is committed to using innovative and effective communications throughout our work, including dissemination. We know that existing communications and dissemination methods have fallen short of changing practice and improving patient outcomes. That is why advancing the science of communications and dissemination is a focus of our Research Agenda—to determine how patients and clinicians can best use CER and PCOR results to enhance decision-making and achieve desired outcomes. To underscore this commitment further, we will explore ways to make dissemination planning a requirement for the primary research applications we will consider.

The Board’s Communication, Outreach and Engagement Committee, the Methodology Committee’s Dissemination Work Group, and the PCORI-AHRQ joint Dissemination Work Group will continue to provide guidance and oversight as staff take on more of the operational duties.

### PCORI’s Path from Priorities to Research Patients Can Use



### 3. Moving Toward a More Targeted Research Portfolio

As noted earlier, our National Priorities for Research and initial Research Agenda were intentionally drafted to be broad so as not to exclude critical opportunities and avenues for investigation early in the process. There always has been an expectation, however, of moving toward greater specificity in the conditions to be studied based on ongoing interaction with stakeholders and on the research proposals they will submit for funding.

Along with this organic path to a more targeted research portfolio, we plan a series of initiatives to drive the discussion about greater specificity, including a series of grants to support conferences on particular research needs with long-lasting impact; a high-level brainstorming workshop on how best to move toward more targeted research priorities; and the advisory groups noted above as a planned engagement tactic.

PCORI has accomplished a great deal in the past 14 months. As this report summarizes, we have built a foundation for a major new research institute; established strong links with patients, clinicians, and other stakeholders who will ultimately drive our work; drafted a road map for our research efforts; and moved to develop the necessary methodological framework for carrying out the research we will support.

We still have important work ahead. When we next report to Congress, the President, and the public, we will have completed a wide range of start-up activities, have a research road map in hand, and have funded dozens of primary research projects. We will be looking forward to receipt of the initial sets of data that we believe will help to transform the kinds of information patients, their caregivers, and clinicians have at hand to help them make better-informed health care decisions. We will have moved to establish the plans and partnerships that will eventually translate the research we support into practice. And we will be that much closer to our goal—improved health outcomes that are most meaningful to patients.

**“There is a large component of research being done on people, instead of with people. This is research that is going to have to be done with people, and those should be the guidelines and the principles that guide all of PCORI’s research...”**

—Adolph Falcon, SVP, National Alliance for Hispanic Health

## Financial Highlights

The Patient-Centered Outcomes Research Institute is funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF). The federal government distributes the funding to the PCORTF annually at the beginning of the government fiscal year (October 1 to September 30) and, effective with the government fiscal year beginning on October 1, 2010, the Treasury Department transfers 20% of the annual appropriation to the U.S. Department of Health and Human Services and the Agency for Healthcare Research and Quality for dissemination of PCORI-funded research findings and to build capacity for comparative clinical effectiveness research.

PCORI's 2012 budget is aligned with its strategic pillars—research, rigorous methods, stakeholder engagement, dissemination, and infrastructure development. Top organizational priorities for the year include expanding stakeholder engagement, developing patient-centered National Priorities for Research and a Research Agenda, funding the first round of primary research, and design and implementation of a sound infrastructure for operations.

### 2012 Budget

(All dollars in thousands)

	Amount	%
<b>Program Services</b>		
Contracts:		
Research	\$120,584	76%
Rigorous Methods	7,300	5%
Contracts Total	127,884	81%
Patient and Stakeholder Engagement	8,035	5%
Dissemination	2,435	2%
<b>Total Program Services</b>	138,354	88%
<b>Supporting Services</b>		
PCORI General Administration	16,393	10%
Infrastructure Development	3,618	2%
<b>Total Supporting Services</b>	20,011	12%
<b>Total Expenses</b>	\$158,365	100%

### Statement of Financial Position

(All dollars in thousands)

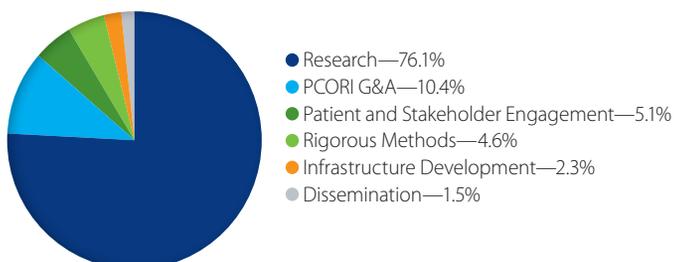
	2011	2010	Increase	% Change
Assets	\$163,485	\$49,874	\$113,611	228%
Liabilities	\$ 2,514	\$ 315	\$ 2,199	697%
Net Assets	\$160,971	\$49,558	\$111,412	225%

### Statement of Activities

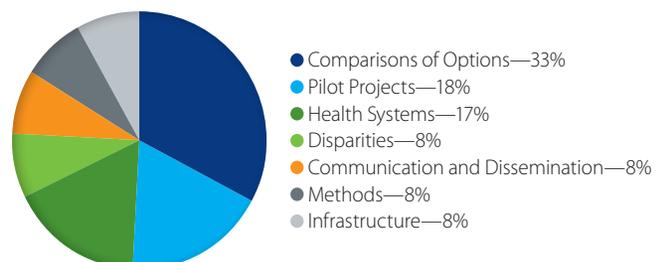
(All dollars in thousands)

	2011	2010	Increase	% Change
Revenues	\$120,024	\$50,009	\$ 70,015	140%
Expenses	\$ 8,612	\$ 451	\$ 8,161	1812%

### Budget Distribution—2012 Forecast



### 2012 Projections for Research Funding



## Patient-Centered Outcomes Research Institute

Research Contracts Awarded January 2011–February 2012

Contract Scope of Work	Contracting Organization	Principal Investigator	Contract Amount
Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcome Research <i>(Stakeholder Interviews)</i>	University of Maryland, Pharmaceutical Health Services Research Department	Daniel Mullins, PhD	\$125,000
Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcome Research <i>(Literature Review)</i>	Mayo Clinic, Knowledge and Evaluation Research Unit	M. Hassan Murad, MD, MPH	\$176,025
Evidence for Eliciting the Patient’s Perspective in Patient-Centered Outcome Research <i>(Stakeholder Interviews)</i>	Oregon Health & Science University, The Center for Evidence-Based Policy	Pam Curtis, MS	\$295,212
Review of Guidance Documents for Selected Methods in PCOR <i>(Patient-Reported Outcomes Measures)</i>	Oxford Outcomes, Ltd., Patient Reported Outcomes	Andrew Lloyd, PhD	\$69,705
Review of Guidance Documents for Selected Methods in PCOR <i>(Patient-Reported Outcomes Measures)</i>	Northwestern University/ UNC Chapel Hill	Zeeshan Butt, PhD Bryce Reeve, PhD	\$83,908
Review of Guidance Documents for Selected Methods in PCOR	Johns Hopkins University	Tianjing Li, MD, MHS, PhD	\$66,150
Review of Guidance Documents for Selected Methods in PCOR	Johns Hopkins University— School of Medicine	Ravi Varadhan, PhD	\$69,231
Review of Guidance Documents for Selected Methods in PCOR	Berry Consultants	Scott Berry	\$74,200
Review of Guidance Documents for Selected Methods in PCOR	Brown University	Constantine Gatsonis, PhD	\$77,869
Review of Guidance Documents for Selected Methods in PCOR	Brigham and Women’s Hospital and Harvard Medical School	Josh Gagne, PharmD, ScD	\$115,664
Review of Guidance Documents for Selected Methods in PCOR	Outcome Science	Richard Giklich, MD	\$87,066
Review of Guidance Documents for Selected Methods in PCOR	University of California San Diego (UCSD)	Lucila Ohno-Machado, MD, PhD	\$116,442
Methods for Setting Priorities in Research <i>(White Paper)</i>	Hayes, Inc.	Petra Nass, PhD	\$30,100
Methods for Setting Priorities in Research <i>(White Paper)</i>	NORC at the University of Chicago	David Rein, PhD	\$34,906
Methods for Setting Priorities in Research <i>(White Paper)</i>	Duke Evidence-based Practice Center	Gillian Sanders Evan Myers, MD, MPH	\$35,000
Methods for Setting Priorities in Research <i>(White Paper)</i>	Medical College of Wisconsin	Theodore Kotchen, MD	\$12,484
Analysis of Input Received on Working Definition of “Patient-Centered Outcomes Research”	NORC at the University of Chicago	Wilhelmine Miller, MS, PhD	\$90,797
Prioritizing Future Research through Examination of Patient-Centered Comparative Effectiveness Research <i>(White Paper)</i>	University of North Carolina at Chapel Hill	Timothy S. Carey, MD, MPH	\$25,000

## Board of Governors

Debra Barksdale, PhD, RN  
Kerry Barnett, JD  
Lawrence Becker  
Carolyn M. Clancy, MD  
Francis S. Collins, MD, PhD  
Leah Hole-Curry, JD  
Allen Douma, MD  
Arnold Epstein, MD  
Christine Goertz, DC, PhD  
Gail Hunt  
Robert Jesse, MD, PhD  
Harlan Krumholz, MD  
Richard E. Kuntz, MD, MSc  
Sharon Levine, MD  
Freda Lewis-Hall, MD  
Steven Lipstein, MHA (Vice Chair)  
Grayson Norquist, MD, MSPH  
Ellen Sigal, PhD  
Eugene Washington, MD, MSc (Chair)  
Harlan Weisman, MD  
Robert Zwolak, MD, PhD

## Board of Governors Committees

### Finance, Audit and Administration

Kerry Barnett, JD (Chair)  
Lawrence Becker  
Allen Douma, MD  
Freda Lewis-Hall, MD  
Robert Zwolak, MD, PhD

### Program Development

Richard E. Kuntz, MD, MSc (Chair)  
Carolyn M. Clancy, MD  
Francis S. Collins, MD, PhD  
Leah Hole-Curry, JD  
Arnold Epstein, MD  
Christine Goertz, DC, PhD  
Gail Hunt  
Harlan Krumholz, MD

### Communications, Outreach and Engagement

Sharon Levine, MD (Chair)  
Debra Barksdale, PhD, RN  
Robert Jesse, MD, PhD  
Grayson Norquist, MD, MSPH  
Ellen Sigal, PhD  
Harlan Weisman, MD

## Methodology Committee

Naomi Aronson, PhD  
Ethan Basch, MD, MSc  
Alfred O. Berg, MD, MPH  
David Flum, MD, MPH  
Sherine Gabriel, MD, MSc (Chair)  
Steven Goodman, MD, MHS, PhD  
Mark Helfand, MD, MS, MPH  
John Ioannidis, MD, DSc  
Michael S. Lauer, MD  
David O. Meltzer, MD, PhD  
Brian S. Mittman, PhD  
Robin Newhouse, PhD, RN  
Sharon-Lise Normand, PhD (Vice Chair)  
Sebastian Schneeweiss, MD, ScD  
Jean R. Slutsky, PA, MSPH  
Mary Tinetti, MD  
Clyde Yancy, MD, MSc

## Methodology Committee Working Groups

### Patient-Centeredness Working Group

Ethan Basch, MD, MSc (Chair)  
Mary Tinetti, MD (Co-Chair)  
Naomi Aronson, PhD  
Brian S. Mittman, PhD

### Research Prioritization Working Group

David O. Meltzer, MD, PhD (Chair)  
John Ioannidis, MD, MSc  
Jean R. Slutsky, PA, MSPH  
Clyde Yancy, MD, MSc

### Research Methods Working Group

Steven Goodman, MD, MHS, PhD (Chair)  
Robin Newhouse, PhD, RN (Co-Chair)  
Michael S. Lauer, MD  
Sebastian Schneeweiss, MD, ScD  
Sharon-Lise Normand, PhD

### Report Assimilation Working Group

Mark Helfand, MD, MS, MPH (Chair)  
Alfred O. Berg, MD, MPH  
David Flum, MD, MPH  
Sherine Gabriel, MD, MSc  
Sharon-Lise Normand, PhD

## Special Committees

### Dissemination Work Group

Carolyn M. Clancy, MD (Co-Chair)  
Sharon Levine, MD (Co-Chair)  
Lawrence Becker  
Allen Douma, MD  
Christine Goertz, DC, PhD  
Howard E. Holland, Director, AHRQ Office of  
Communications and Knowledge Transfer  
Gail Hunt  
Freda Lewis-Hall, MD  
Steven Lipstein, MHA  
Brian S. Mittman, PhD  
Robin Newhouse, PhD, RN  
Grayson Norquist, MD, MSPH  
Jean R. Slutsky, PA, MSPH

### Subcommittee on Scientific Publications

Debra Barksdale, PhD, RN (Chair)  
Harlan Krumholz, MD  
Sharon-Lise Normand, PhD  
Michael S. Lauer, MD  
Anne Beal, MD, MPH  
Joe Selby, MD, MPH

### Standing Committee on Conflicts of Interest

Lawrence Becker, PCORI Board Member (Chair)  
Robert Zwolak, MD, PhD, PCORI Board Member  
Sherine Gabriel, MD, MSc, PCORI Member  
Bernard Lo, MD, Ethicist, UC San Francisco—  
Professor Emeritus  
Annette Bar-Cohen, MPH, Consumer Advocate,  
National Breast Cancer Coalition  
Art Levin, MPH, Consumer Advocate, Center for  
Medical Consumers  
Mark Feldstein, PhD, Media Representative,  
University of Maryland  
Karl Sleight, JD, Counsel, Harris Beach, LLC  
Gail Shearer, MPP, Senior Advisor, PCORI

### PCORI Pilot Project Selection Committee

Grayson Norquist, MD, MSPH (Chair)  
Christine Goertz, DC, PhD (Advisor, non-voting)  
Kerry Barnett, JD  
Carolyn M. Clancy, MD  
Arnold Epstein, MD  
Gail Hunt  
Steven Lipstein, MHA  
Sherine Gabriel, MD, MSc  
Clyde Yancy, MD, MSc  
Joe Selby, MD, MPH

## Staff

Anne Beal, MD, MPH, Chief Operating Officer  
Martin Duenas, MPA, Director, Contracts Management  
Lori Frank, PhD, Director, Engagement Research  
Judith Glanz, Director, Patient Engagement  
Pam Goodnow, Director, Finance  
Susan Hildebrandt, MA, Director, Stakeholder Engagement  
Joe Selby, MD, MPH, Executive Director  
Sue Sheridan, MBA, MIM, Deputy Director, Patient Engagement  
William Silberg, Director, Communications  
Melissa Stern, MBA, Director, Strategic Initiatives

# Patient-Centered Outcomes Research Institute

2011 Annual Report

## APPENDIX TABLE OF CONTENTS

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## PCORI Conflict of Interest Disclosures

The Patient Protection and Affordable Care Act, which authorized the establishment of the Patient-Centered Outcomes Research Institute, requires PCORI to disclose any conflicts of interest of its Board of Governors, Methodology Committee, and executive staff. The Act defines “conflict of interest” as: “An association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual’s decision in matters related to the Institute or the conduct of activities under this section.” Below are the associations reported by PCORI’s Board of Governors, Methodology Committee, and executive staff that fit within the definition of a “conflict of interest” specified by the law.

### Board of Governors

#### Debra Barksdale, PhD, RN

(As of September 29, 2011)

##### FINANCIAL ASSOCIATIONS:

- University of North Carolina at Chapel Hill (Employer)
- NIH—receive grant for research
- Robert Wood Johnson Foundation—Executive Nurse Fellow

##### PERSONAL ASSOCIATIONS:

- National Organization of Nurse Practitioner Faculties—President-Elect
- National League for Nursing—member
- American Academy of Nurse Practitioners—member
- International Family Nursing Association—member
- American Association of Colleges of Nursing, Practice Leadership Network—member
- American Nurses Association—member
- Southern Nurses Research Society—member
- American Heart Association—member
- North Carolina Nurses Association—member
- Sigma Theta Tau International Honor Society of Nursing—member

#### Kerry Barnett, JD

(As of October 7, 2011)

##### FINANCIAL ASSOCIATIONS:

- The Regence Group and Affiliates (Employer)

##### PERSONAL ASSOCIATIONS:

- United Way

#### Lawrence Becker

(As of October 11, 2011)

##### FINANCIAL ASSOCIATIONS:

- Xerox Corporation (Employer)
- Stock ownership:
  - Aetna, Inc.
  - GE
  - Johnson & Johnson, Inc.
  - Pfizer, Inc.
  - SPDR Biotech
  - The Travelers Companies, Inc.
- Benfield Group
- LSB Consultants, LLC—company owned by wife

##### PERSONAL ASSOCIATIONS:

- ERISA Industry Council—Board member
- The National Quality Forum—Board member
- Rochester Regional Health Information Organization—Board member

#### Carolyn M. Clancy, MD

(As of December 21, 2011)

##### FINANCIAL ASSOCIATIONS:

- Director, Agency for Healthcare Research and Quality (Employer)

##### PERSONAL ASSOCIATIONS:

- Institute of Medicine—member
- American College of Physicians—Master
- George Washington University School of Medicine—Clinical Associate Professor

#### Francis S. Collins, MD, PhD

(As of December 21, 2011)

##### FINANCIAL ASSOCIATIONS:

- Director, National Institutes of Health (Employer)

##### PERSONAL ASSOCIATIONS:

- Institute of Medicine—member
- National Academy of Sciences—member

#### Leah Hole-Curry, JD

(As of November 21, 2011)

##### FINANCIAL ASSOCIATIONS:

- Washington State Department of Labor and Industries—Medical Administrator (Employer)

##### PERSONAL ASSOCIATIONS:

- None Identified

#### Allen Douma, MD

(As of September 28, 2011)

##### FINANCIAL ASSOCIATIONS:

- None Identified

##### PERSONAL ASSOCIATIONS:

- AARP—Board member
- Jefferson Regional Health Alliance—Board member

#### Arnold Epstein, MD

(As of October 19, 2011)

##### FINANCIAL ASSOCIATIONS:

- Harvard University—faculty (Employer)
- Brigham and Women’s Hospital—staff (Employer)
- New England Journal of Medicine—consultant
- Todd & Weld LLP—consultant
- Thornton & Naumes, LLP—consultant
- Levy Phillips & Konigsberg, LLP—consultant
- Partners HealthCare, Massachusetts General Hospital—spouse’s employment

##### PERSONAL ASSOCIATIONS:

- Center for Health Care Strategies—member of the Board of Trustees
- AcademyHealth—member
- American Association of Professors—member
- American Society for Clinical Investigation—member
- Institute of Medicine—member

#### Christine Goertz, DC, PhD

(As of October 6, 2011)

##### FINANCIAL ASSOCIATIONS:

- Palmer College of Chiropractic—Vice Chancellor (Employer)
- American Chiropractic Association—consultant
- Healthwise—consultant
- University of Missouri, Kansas City—consultant (NIH grant)
- Kansas City University of Medicine and Biosciences—consultant
- Life University—speaking honoraria
- Quality Insights of Pennsylvania—consultant

##### PERSONAL ASSOCIATIONS:

- American Medical Association
- Measures, Instrumentation, and Evaluation Advisory Committee—member
- Health Care Professionals Advisory Committee—alternate member
- Iowa Chiropractic Society—member
- Journal of Manipulative and Physiological Therapeutics—Editorial Board
- American Public Health Association—member
- Women’s Leadership Council of the Quad Cities—United Way—member

**Gail Hunt***(As of September 30, 2011)***FINANCIAL ASSOCIATIONS:**

- National Alliance for Caregiving—CEO (Employer)
- The Alliance receives grants from healthcare-related groups

**PERSONAL ASSOCIATIONS:**

- National Center on Senior Transportation—Chair of the Board of Directors
- Long Term Quality Alliance—Secretary of the Board of Directors
- Center for Aging Services Technology—Commissioner
- Vinson Hall Corporation—Member of the Board of Directors
- Center for Advancing Health—Member of the Board of Trustees
- Advisory Panel on Medicare Education—member
- American Society on Aging—member
- National Council on the Aging—member
- Gerontological Society of America—member
- International Alliance of Patient Organizations—member
- International Federation on Aging—member

**Robert Jesse, MD, PhD***(As of October 24, 2011)***FINANCIAL ASSOCIATIONS:**

- Department of Veterans Affairs—Principal Deputy Under Secretary for Health (Employer)
- Virginia Commonwealth University Health System (Employer)

**PERSONAL ASSOCIATIONS:**

- American Heart Association—Fellow
- Richmond Metro Chapter of the American Heart Association—President
- The Virginia BioTechnology Research Partnership Authority Board—Board member
- Vital Sensors, Inc.—Board member
- American Board of Internal Medicine—diplomate
- American College of Cardiology—Fellow
- Society of Chest Pain Centers—Board member

**Harlan Krumholz, MD***(As of October 19, 2011)***FINANCIAL ASSOCIATIONS:**

- Yale University—Professor of Medicine (Employer)
- VHA Inc.—consultant
- United Healthcare—Chair, Scientific Advisory Committee

- Image COR, LLC—Founder
- American Heart Association—editor
- Massachusetts Medical Society—editor
- American Board of Internal Medicine—Board member
- Institute of Healthcare Improvement—Chair, Scientific Advisory Group
- Medtronic, Inc.—Principal Investigator on grant through Yale University

**PERSONAL ASSOCIATIONS:**

- American College of Cardiology—Board member
- CV Outcomes, Inc.—Secretary
- Lifetech Development Partners—consultant and director
- C2N Diagnostics LLC—consultant

**Richard E. Kuntz, MD, MSc***(As of October 4, 2011)***FINANCIAL ASSOCIATIONS:**

- Medtronic, Inc. (Employer)
- Tengion—Board member (receives fee as Director)

**PERSONAL ASSOCIATIONS:**

- Minnesota Medical Foundation
- Case Western Reserve Medical School Board of Visitors
- Chiari & Syringomyelia Foundation

**Sharon Levine, MD***(As of November 4, 2011)***FINANCIAL ASSOCIATIONS:**

- The Permanente Medical Group, Inc.—Associate Executive Director (Employer)

**PERSONAL ASSOCIATIONS:**

- Reagan-Udall Foundation—Board member
- California Association of Physician Groups—Board member
- Public Health Institute—Board chair
- Medical Board of California—Board member
- Insure the Uninsured Project—Board member (as of 1/2012)

**Freda Lewis-Hall, MD***(As of October 27, 2011)***FINANCIAL ASSOCIATIONS:**

- Pfizer, Inc. (Employer)
- Investments:
  - Pfizer, Inc
  - Pfizer Savings Plan
  - Pfizer Supplemental Savings Plan
  - Pfizer/Pharmacia Retirement Plan
  - Eli Lilly Defined Benefit Pension Fund
  - Bristol-Myers Squibb Defined Benefit Pension Plan
  - Bristol-Myers Squibb Savings Plan

- Vertex 401k Plan
- Vertex Pharmaceuticals, Inc.
- Howard University Retirement Plan

**PERSONAL ASSOCIATIONS:**

- Society for Women's Health Research—Board member
- Power To End Stroke, American Heart Association—Board member
- Foundation for the National Institutes of Health—Board member
- Fellows of Harvard Medical School—Board member
- New York Academy of Medicine—Board member
- Institute of Medicine—member
- American Psychiatric Association—member
- Healthcare Businesswomen Association—member

**Steven Lipstein, MHA (Vice Chair)***(As of November 1, 2011)***FINANCIAL ASSOCIATIONS:**

- BJC HealthCare—President and CEO (Employer)
- Emory University Healthcare Innovation Program—Advisory Board member

**PERSONAL ASSOCIATIONS:**

- Washington University—Trustee
- Missouri Hospital Association—Board member
- St. Louis Regional Health Commission—member

**Grayson Norquist, MD, MSPH***(As of September 27, 2011)***FINANCIAL ASSOCIATIONS:**

- University of Mississippi Medical School—Chair, Department of Psychiatry (Employer)
- Delta Health Alliance—receive grant funding for salary

**PERSONAL ASSOCIATIONS:**

- American Psychiatric Association (APA)—fellow
- APA Council on Research and Quality—member
- American Psychiatric Foundation (component of APA)—Board of Directors
- Academy Health—fellow
- Mississippi Coast Interfaith Disaster Task Force
- Mississippi Psychiatric Association—member of Executive Board
- Tougaloo College
- UCLA—Department of Psychiatry and Biobehavioral Sciences

## Ellen Sigal, PhD

(As of October 31, 2011)

### FINANCIAL ASSOCIATIONS:

- Stand Up To Cancer—Member of Scientific Advisory Committee

### PERSONAL ASSOCIATIONS:

- Friends of Cancer Research—Founder and Chair of Board
- Reagan-Udall Foundation—Vice-Chair of Board
- Foundation for the National Institutes of Health—Chair of Public-Private Partnership Committee and Board member
- American Association for Cancer Research Foundation—Board member
- Duke University Cancer Center Board of Overseers—Board member
- Research America—Board member
- M. D. Anderson Cancer Center—Advisory Board
- The Sidney Kimmel Cancer Center, Johns Hopkins—Member, Advisory Council

## Eugene Washington, MD, MSc (Chair)

(As of November 1, 2011)

### FINANCIAL ASSOCIATIONS:

- David Geffen School of Medicine, UCLA—Vice Chancellor and Dean (Employer)
- Robert Wood Johnson Foundation—Board member
- The California Wellness Foundation—Board member

### PERSONAL ASSOCIATIONS:

- None Identified

## Harlan Weisman, MD

(As of September 15, 2011)

### FINANCIAL ASSOCIATIONS:

- Johnson & Johnson—Chief Science and Technology Officer, Medical Devices & Diagnostics (Employer)  
-Owns stock and has options

### PERSONAL ASSOCIATIONS:

- Board member of the following organizations:
  - University of Pennsylvania—Center for Bioethics External Advisory Board
  - Johns Hopkins University School of Medicine; Institute for Basic Biomedical Sciences Advisory Council
  - Chief Technology Officer Advisory Board, Research and Technology
  - Executive Council of the Corporate Executive Board
  - McKinsey Product Development Leaders Roundtable

- Memberships in Professional Societies:
  - American College of Cardiology (Fellow)
  - American College of Chest Physicians (Fellow)
  - American College of Physicians
  - American Federation of Clinical Research
  - American Heart Association
  - Council on Clinical Cardiology (Fellow)
  - Council on Arteriosclerosis, Thrombosis, and Vascular Biology (Fellow)
  - American Medical Association
  - New Jersey Medical Society/Mercer County Medical Society

## Robert Zwolak, MD, PhD

(As of September 18, 2011)

### FINANCIAL ASSOCIATIONS:

- Dartmouth-Hitchcock Clinic (Employer)
- US Department of Veterans Affairs (Employer)
- Society for Vascular Surgery—honoraria received for teaching
- American Podiatric Medical Association—honorarium received for invited lectures
- Medical College of South Carolina—honorarium for 2-day visiting professorship
- Emory University—honorarium for 2-day visiting professorship
- EVA Corporation—medical device manufacturer—owns stock

### PERSONAL ASSOCIATIONS:

- Board of Directors Intersocietal Commission for Accreditation of Carotid Stent Facilities
- AMA/Specialty Society Relative Value Update Committee—prior full member, current member of two workgroups (lesser involvement than full committee member)
- Society for Vascular Surgery—Immediate Past-President, current Board of Directors member
- American College of Surgeons—member Board of Governors in 2010, current member of several committees and workgroups of lesser status than Governor
- Dartmouth Medical School—Professor (no salary)

## Methodology Committee

## Naomi Aronson, PhD

(As of February 13, 2012)

### FINANCIAL ASSOCIATIONS:

- Blue Cross Blue Shield Association, Technology Evaluation Center (Employer)  
-Under contract with Agency for Health Research and Quality

### PERSONAL ASSOCIATIONS:

- GAPPNET Planning Committee
- Health Technology Assessment International Health Policy Forum
- Institute of Medicine Genomics Roundtable
- Steering Committee of the Chicago Area—DEClIDE Research Center
- National Business Group on Health Committee on Evidence-Based Benefit Design
- University of Toronto's internal Canada Foundation for Innovation—External Reviewer in 2012  
-Pertinent Previous: Institute of Medicine Forum on Drug Discovery Translation and Development (2005–2008)

## Ethan Basch, MD, MSc

(As of March 7, 2012)

### FINANCIAL ASSOCIATIONS:

- Memorial Sloan-Kettering Cancer Center, Associate Attending Physician (Employer)
- Blue Cross Blue Shield (Consultant, Progression Free Survival Report)

### PERSONAL ASSOCIATIONS:

- Member, American Society of Clinical Oncology
- Co-Chair, Alliance Health Outcomes Committee
- Member, American Medical Informatics Association
- Member, International Society of Pharmacoeconomics and Outcomes Research
- Board member, International Society for Quality and Life Research

## Alfred O. Berg, MD, MPH

(As of February 13, 2012)

### FINANCIAL ASSOCIATIONS:

- University of Washington, Seattle, NIH Investigator (Employer)

### PERSONAL ASSOCIATIONS:

- Member, American Academy of Family Physicians
- Member, Society of Teachers of Family Medicine

**David Flum, MD, MPH***(As of March 16, 2012)***FINANCIAL ASSOCIATIONS:**

- University of Washington—Department of Surgery (Employer)
- Surgical Consulting (Legal Consulting)
- Benchmark (Privately Owned Business)
- Group Health Cooperative (Wife's Employer)
- Shire (Received consulting fees and travel expense for Diverticular Disease Scientific Need/Working Group on 10/28/11)
- Applied Medical (received fee for symposium presentation on 10/25/11)
- American College of Phlebology (received honorarium and travel expenses for speaking at annual meeting 11/4/11)

**PERSONAL ASSOCIATIONS:**

- American College of Surgeons
- Washington State Chapter—American College of Surgeons
- American Society for Metabolic and Bariatric Surgery
- American Surgical Association
- Henry N. Harkins Surgical Society
- Seattle Surgical Society
- Surgical Outcomes Club

**Sherine Gabriel, MD, MSc (Chair)***(As of February 29, 2012)***FINANCIAL ASSOCIATIONS:**

- Mayo Clinic (Employer)
- Genentech
- Hoffman-LaRoche
- NIH

**PERSONAL ASSOCIATIONS:**

- Member, FDA/CDER Drug Safety and Risk Management Advisory Committee (2010–present)
- Chair, FDA/CDER Drug Safety and Risk Management Advisory Committee (2011–present)
- Member, External Advisory Board, University of Puerto Rico Post-doctoral Master of Science in Clinical Research Program, School of Medicine and School of Health Professions (2006–present)
- Member, Executive Board, Observational Medical Outcomes Partnership, Foundation for the NIH (2008–present)
- Member, Scientific Advisory Board, Excellence in Rheumatology (2010–present)
- Member, International Coordination Council, Bone and Joint Decade/Initiative (2010–present)
- Chair, CTSA Academic-Industry Working Group (2010–present)

- Member, Steering Committee, Actemra Cardiovascular Outcomes Trial (ENTRACTE), Roche (2009–present)
- Member, Pharmacoepidemiology Advisory Board, Genentech (2009–present)
- Member, External Research Education Advisory Board, University of Kentucky CTSA (2011–present)
- Member, External Research Education Advisory Committee, Georgetown University (2011–present)
- Member, Oversight Board, Wellcome Trust, HRB Dublin Centre for Clinical Research (2011–present)
- Chair, Methodology Committee, Patient-Centered Outcomes Research Institute (2011–present)

**Steven Goodman, MD, MHS, PhD***(As of April 27, 2012)***FINANCIAL ASSOCIATIONS:**

- Stanford University (Employer)
- National Blue-Cross/Blue Shield, Scientific Advisor to Technology Assessment Program
- The American College of Physicians, Associate Editor for Annals of Internal Medicine

**PERSONAL ASSOCIATIONS:**

None Identified

**Mark Helfand, MD, MS, MPH***(As of February 10, 2012)***FINANCIAL ASSOCIATIONS:**

- Staff Physician, Portland VA Medical Center (Employer)
- Professor, Oregon Health & Science University (Employer)
- Employer Receives Grants through
  - Department of Veterans Affairs
  - Agency for Healthcare Research & Quality
  - National Institutes for Health
- Contracts at Oregon Health & Science University through Oregon Evidence-based Practice Center
  - Yale University Open Data Access (YODA) Project, primary funding to Yale is Medtronics
  - Drug Evaluation Review Program, Center for Evidenced-based Policy, OHSU, primary funders are several U.S. state governments and CMS, DHSS
  - American Pain Society
- Recently Completed Contracts with
  - American College of Chest Physicians
  - Knight Cancer Institute, OHSU, primary funding was Susan G Foundation
- Consulting
  - Consumer Union
  - Society for Medical Decision Making

**PERSONAL ASSOCIATIONS:**

- Editor in Chief, Medical Decision Making, Society for Medical Decision Making
- Member, Academy Health
- Advisory Board, U.S. Cochrane Center
- Fellow, American College of Physicians
- Member, Society for General Internal Medicine

**John Ioannidis, MD, DSc***(As of March 21, 2012)***FINANCIAL ASSOCIATIONS:**

- Professor, Stanford University School of Medicine (Employer)

**PERSONAL ASSOCIATIONS:**

- Editor-in-chief, European Journal of Clinical Investigation
- Editorial member of 26 international peer-reviewed journals

**Michael S. Lauer, MD***(As of April 17, 2011)***FINANCIAL ASSOCIATIONS:**

- National Institutes of Health (Employer)
- Cleveland Clinic
  - Cleveland Clinic Health Systems Savings Investment Plan
- Putnam College Fund
- UptoDate Inc.

**PERSONAL ASSOCIATIONS:**

None Identified

**David O. Meltzer MD, PhD***(As of April 22, 2012)***FINANCIAL ASSOCIATIONS:**

- University of Chicago (Employer)
- Norvartis
- CVS
- ABIM
- Peoplechart
- Cubist
- InHealth
- Grants from:
  - National Institutes for Health
  - Agency for Healthcare Research and Quality
  - Robert Wood Johnson Foundation
  - National Pharmaceutical Council
- Stocks holding in Acadia Pharmaceuticals and Valeant Pharmaceuticals

**PERSONAL ASSOCIATIONS:**

- Member of ABIM, SGIM, SHM, MDM
- University of Chicago

**Brian S. Mittman, PhD***(As of March 1, 2012)***FINANCIAL ASSOCIATIONS:**

- VA Greater Los Angeles Healthcare System, U.S. Dept. of Veterans Affairs (Part-time Employee)
- Sepulveda Research Corporation (Part-time Employee)
- UCLA (Consultant, research grants and fellowship training)
- University of Washington in St. Louis (Consultant, training program)
- Westat (Consultant, AHRQ—funded Health Care Innovations Exchange Programs)
- U.S. Department of Energy Oak Ridge Institute for Science and Education (Consultant, CMS-funded Innovation Advisors Program)
- Purdue Pharmaceuticals (Consultant, Development of FDA-mandated Risk Evaluation and Mitigation Strategy for prescription misuse)
- National Institutes of Health (Consultant to the Hill Group)
- Institute for Healthcare Improvement (Consultant)
- Rand Corporation (Consultant)

**PERSONAL ASSOCIATIONS:**

- Member, Association of American Medical Colleges, Advisory Panel on Research
- Member, AcademyHealth, Methods Council
- Member, Knowledge Translation Canada, International Scientific Advisory Board
- Member, Singapore Ministry of Health, International Scientific Advisory Board for Health Services Research
- Member, University of Miami Center for Prevention Implementation Methodology, Scientific Advisory Board

**Robin Newhouse, PhD, RN***(As of February 14, 2012)***FINANCIAL ASSOCIATIONS:**

- University of Maryland—School of Nursing, Chair, Organizational Systems and Adult Health (Employer)

**PERSONAL ASSOCIATIONS:**

- Chair, Research and Scholarship Advisory Council, Sigma Theta Tau International Honor Society of Nursing
- Research Council Member, American Nurses Credentialing Center
- Chair, Review Committee for Student Posters, 2012 AcademyHealth Research Meeting

**Sharon-Lise Normand, PhD****(Vice Chair)***(As of March 19, 2012)***FINANCIAL ASSOCIATIONS:**

- Harvard Medical School (Employer)
- Provides statistical consulting services for
  - Yale–New Haven Hospital System
  - The Massachusetts Medical Society
  - Institute for Clinical Evaluative Sciences (not-for-profit Canadian Organization)
- Brown University, Department of Biostatistics (Husband's employer, has been awarded a grant from Methodology Committee to provide standards for diagnostic testing)

**PERSONAL ASSOCIATIONS:**

- Scientific Advisory Board member, Institute of Clinical Evaluative Sciences, Toronto, Canada
- Board member, Frontier Science and Technology
- Product Oversight Committee member, American Board of Internal Medicine
- Medicare Evidence Development and Coverage Advisory Committee member

**Sebastian Schneeweiss, MD, ScD***(As of February 9, 2012)***FINANCIAL ASSOCIATIONS:**

- Brigham and Women's Hospital
- Most health care products
- Harvard School of Public Health
- WHISCON LLC
- Booz & Co.

**PERSONAL ASSOCIATIONS:**

- Member of
  - ISPE
  - ASCPT
- Fellow of
  - The American College of Pharm
  - The American College of Epidemiology

**Jean R. Slutsky, PA, MSPH***(As of March 21, 2012)***FINANCIAL ASSOCIATIONS:**

- Agency for Healthcare Research and Quality (Employer)

**PERSONAL ASSOCIATIONS:**

- None Identified

**Mary Tinetti, MD***(As of March 2, 2012)***FINANCIAL ASSOCIATIONS:**

- Yale University (Employer)
- National Institutes of Health
- Hartford Foundation
- Yale–New Haven Hospital

**PERSONAL ASSOCIATIONS:**

- None Identified

**Clyde Yancy, MD, MSc****FINANCIAL ASSOCIATIONS:**

- Northwestern University, Feinberg School of Medicine (Employer)
  - Aligned with Northwestern Memorial Hospital Corporation
- Northwestern Medical Family Foundation (Employer)
  - Aligned with Northwestern Memorial Hospital Corporation
- National Institutes of Health
- Agency for Healthcare Research and Quality
- FDA (Special government employee, chair, Cardiovascular Devices Panel)

**PERSONAL ASSOCIATIONS:**

- Former President of the American Heart Association (2009–2010)
- Committee Member, American Hospital Association
- Committee Member, American College of Cardiology
- Member, American College of Physicians
- Member, the Heart Failure Society of America
- Member, the Heart Rhythm Society of America
- Member, the Association of Black Cardiologists

## PCORI Staff

### **Anne Beal, MD, MPH**

*(As of January 29, 2012)*

#### **FINANCIAL ASSOCIATIONS:**

- Investments: Aetna

#### **PERSONAL ASSOCIATIONS:**

- None Identified

### **Martin Dueñas, MPA**

*(As of March 14, 2012)*

#### **FINANCIAL ASSOCIATIONS:**

- Investments: Merck, Entremed

#### **PERSONAL ASSOCIATIONS:**

- None Identified

### **Lori Frank, PhD**

*(As of March 10, 2012)*

#### **FINANCIAL ASSOCIATIONS:**

- None Identified

#### **PERSONAL ASSOCIATIONS:**

- Member, Alzheimer's Foundation of America, Memory Advisory Board

### **Judith Glanz**

*(As of January 9, 2012)*

- None Identified

### **Pam Goodnow**

*(As of February 14, 2012)*

- None Identified

### **Susan Hildebrandt, MA**

*(As of March 8, 2012)*

- None Identified

### **Joe Selby, MD, MPH**

*(As of September 14, 2011)*

#### **FINANCIAL ASSOCIATIONS:**

- PCORI—Executive Director (salaried position)
- Kaiser Permanente—as former employee receives retirement payments

#### **PERSONAL ASSOCIATIONS:**

- American Diabetes Association—member
- Stanford Medical School—honorary faculty
- University of California at San Francisco—honorary faculty

### **Sue Sheridan, MBA, MIM**

*(February 27, 2012)*

#### **FINANCIAL ASSOCIATIONS:**

- None Identified

#### **PERSONAL ASSOCIATIONS:**

- Member, Board of Directors, ACGME
- Member, Secretaries Advisory Committee on Infant Mortality
- Board member, Consumers Advancing Patient Safety
- Advisory, Patient Safety Program, World Health Organization

### **William Silberg**

*(January 9, 2012)*

#### **FINANCIAL ASSOCIATIONS**

- Consultant:
  - Medscape (will drop)
  - Columbia Nursing School (will drop)
  - AMA (will drop)

#### **PERSONAL ASSOCIATIONS:**

- Medical Journalism Advisory Board, UNC-Chapel Hill
- Editor-at-Large, American Journal of Preventative Medicine
- Senior Fellow, CHMP, Hunter College
- Member, Medscape CME Advisory Board
- Member, CHMP, National Advisory Council
- Guest Lecturer, NYU Wagner School
- Guest Lecturer, Scientific Committee Workshop

### **Melissa Stern, MBA**

*(January 10, 2012)*

- None Identified

# **Patient-Centered Outcomes Research Institute**

Financial Report  
December 31, 2011

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## Independent Auditor's Report

To the Audit Committee  
Patient-Centered Outcomes Research Institute  
Washington, D.C.

We have audited the accompanying statements of financial position of Patient-Centered Outcomes Research Institute (PCORI) as of December 31, 2011 and 2010, and the related statements of activities, cash flows, and functional expenses for the year ended December 31, 2011, and for the period from November 10, 2010 (Inception) through December 31, 2010. These financial statements are the responsibility of PCORI's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of PCORI's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Patient-Centered Outcomes Research Institute as of December 31, 2011 and 2010, and the changes in its net assets and its cash flows for the year ended December 31, 2011, and for the period from November 10, 2010 (Inception) through December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

In accordance with *Government Auditing Standards*, we have also issued our report dated, April 20, 2012, on our consideration of PCORI's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* and should be considered in assessing the results of our audits.

Management's Discussion and Analysis, on pages 3 – 7, is not a required part of the basic financial statements but is supplementary information to the financial statements under accounting principles generally accepted in the United States of America. We have applied certain limited procedures, which consisted principally of inquiries of management regarding the methods of measurement and presentation of the supplementary information in conformity with the financial statements. However, we did not audit the information and express no opinion on it.

*McGladrey & Pullen, LLP*

Vienna, Virginia  
April 20, 2012

## Patient-Centered Outcomes Research Institute

### Management's Discussion and Analysis

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The Patient-Centered Outcomes Research Institute (PCORI) was established by federal law (42 U.S.C. 1301 et. seq.) in 2010 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.

PCORI is unique both in its mission and how it seeks to fulfill it. 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.

PCORI is a 501(c)(1) non-profit corporation, governed by a 21-member Board of Governors, including the Director of the Agency for Healthcare Research and Quality (AHRQ), the Director of the National Institutes of Health (NIH), and 19 members appointed by the Comptroller General of the United States. By law, the Comptroller must appoint three members representing patients and healthcare consumers, seven members representing physicians and providers, three members representing private payers, three members representing pharmaceutical, device, and diagnostic manufacturers or developers, one member representing quality improvement or independent health services researchers, and two members representing the federal government or the states (including at least one member representing a federal health program or agency).

**Organizational Structure and Stakeholder Collaboration:** PCORI has worked throughout the past year to build a major national health research institute from the ground up, utilizing a rigorous stakeholder-driven process that emphasizes ongoing patient engagement. This work is driven by PCORI's Board, while a 17-member Methodology Committee works to develop and advance the science and methodologies of comparative clinical effectiveness research. Members of the Methodology Committee are experts in their fields of endeavor, including but not limited to health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. PCORI's Board and Methodology Committee have established a number of committees to provide focus for key areas of its work.

#### **Board Committees**

- Communications, Outreach, and Engagement
- Program Development
- Finance, Audit, and Administration

#### **Methodology Committee Working Groups**

- Patient-Centeredness
- Research Prioritization
- Research Methods
- Report Assimilation

#### **Special Committees**

- Dissemination Work Group
- Scientific Publications
- Standing Committee on Conflicts of Interest
- Pilot Project Selection

## Patient-Centered Outcomes Research Institute

### Management's Discussion and Analysis

---

During 2011, the Board established an initial organizational framework, hired an executive director, developed a consensus on PCORI's mission, and delineated processes for defining Patient-Centered Outcomes Research (PCOR), proposing National Research Priorities, establishing a Research Agenda, and producing a methodology report. These efforts have been guided by the mission statement that the Board adopted in July 2011:

***“PCORI helps people make informed healthcare decisions – and improves healthcare delivery and outcomes – by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.”***

This guidance and the involvement of patients and other health care system stakeholders in all phases of research are not only distinguishing characteristics of PCORI's mission – they are essential to broad acceptance of the evidence-based information the research is intended to produce.

**Current Activities:** PCORI has worked continuously to advance its mission by ensuring transparency, credibility, and access in all aspects of its operations. PCORI uses a variety of forums and public comment periods to obtain public input to guide its work. The Board holds open Board meetings every other month, many of them featuring community engagement activities. Board and Methodology Committee members have met with patients, caregivers, and dozens of organizations representing nursing disciplines, medical specialties, medical technology and research fields, as well as patient-advocacy groups. In addition, PCORI has regularly engaged patients, caregivers, clinicians, and others through a series of focus groups on various aspects of its work. The following focus groups were held in the past year:

1. Defining Patient-Centered Outcomes Research
2. Pilot Projects Program
3. Developing National Priorities for Research and a Research Agenda
4. Developing PCORI's First Methodology Report
5. Funding Research

#### **Defining Patient-Centered Outcomes Research**

One of PCORI's foundational tasks was to clearly describe the field of “patient-centered outcomes research,” something not formally defined at the time PCORI was established, as a means of clarifying PCORI's focus and scope of work. This was accomplished through a year-long iterative and transparent process that included a public comment period that generated feedback from nearly 120 organizations and 450 individuals. Additional public input was sought through six focus groups involving patients, caregivers, and the general public. A revised draft was adopted by PCORI's Board in March 2012.

#### **Pilot Projects Program**

PCORI developed its Pilot Projects Program to fund \$26 million in research over two years that would focus on eight areas of interest. The goals for the two-year program are to help establish national priorities for research, the development of PCORI's research agenda, and support the creation of new methods and data collection to advance patient-centered outcomes research. Following a public input period to assess the program's eight proposed focus areas, PCORI issued a request for applications promoting observational methodologies, systematic reviews, mixed methods and qualitative methodologies, simulations, small pragmatic pilot trials, and survey methods. This request generated nearly 1,400 letters of intent and nearly 850 applications. Merit reviews took place in the first quarter of 2012, and a selection committee comprised of Board members will be preparing a recommended slate of projects for funding consideration. The Board intends to announce awards by May.

## **Patient-Centered Outcomes Research Institute**

### **Management's Discussion and Analysis**

---

#### **Developing National Priorities for Research and a Research Agenda**

PCORI must establish National Priorities for Research and a Research Agenda before it can fund primary research. The process of drafting these research roadmaps began in August 2011 under the aegis of the Program Development Committee, which conducted an extensive review of nine previous national efforts to prioritize comparative effectiveness research. The review identified ten common themes that consistently appeared as priority areas for research. These were measured against PCORI's working definition of patient-centered outcomes research to determine five cross-cutting areas that became the PCORI priorities for research. Using the draft priorities as a foundation, the Committee developed an initial research agenda by applying the criteria for research provided in PCORI's establishing legislation. The priorities and agenda were written to be intentionally broad and do not name specific conditions or treatments that PCORI will examine. This approach recognizes that there are many important research questions to be answered and focusing on a narrow set of conditions at the start of PCORI's research funding would exclude certain patients at a very early stage in PCORI's work.

PCORI began incorporating patient and other stakeholder perspectives early in the process, using the experience of the Board and a series of informal meetings with organizations representing patients, as well as other stakeholders, to ensure that the drafts developed for public comment were informed by the health care community. Patient and caregiver focus groups were conducted to provide early input on the developing priorities, and PCORI executive staff and Board members discussed the process with numerous stakeholder organizations, including patient representatives. PCORI released its draft priorities and research agenda for public comment in January 2012, soliciting feedback through a national dialogue event held in Washington, D.C., clinician focus groups, a web-based survey tool, and print and online advertisements placed in a wide range of consumer and professional media.

After reviewing the feedback received, PCORI will publish a report that summarizes the input and subsequent recommendations for changes to the draft priorities and agenda. The Board will consider a revised set of proposed priorities and an agenda during a public teleconference in April, preparatory to issuing initial funding announcements in May.

#### **Developing PCORI's First Methodology Report**

The Methodology Committee conducted activities during 2011 that laid the groundwork to prepare methodological standards for comparative clinical effectiveness and patient-centered outcomes research and a translation table that will provide guidance to the Board in determining which research methods should be used to address specific research questions. Four working groups: Patient-Centeredness, Research Priorities, Research Methods, and Report Assimilation, were established to guide the work. The Committee issued a Request for Information (RFI) to solicit input from methodologists on the translation table. The RFI resulted in the submission of 24 responses, including 17 case studies. The Committee developed requests for proposals to (1) review guidance on selected research methods; (2) review and synthesize evidence for eliciting the patient's perspective in patient-centered outcomes research (through literature review and expert stakeholder interviews); and (3) develop white papers on methods for setting priorities in research. The Committee oversaw a rigorous proposal review process that resulted in the execution of 15 awards to leading research organizations from across the country during 2011. The Committee is in the process of using the reports from these awards to develop the first set of standards that will be in the first Methodology Report, to be submitted to the Board on May 10, 2012.

#### **Funding Research in 2011**

PCORI will make a variety of external funding opportunities available throughout the course of its work. In 2011, the Institute funded 15 contracts in response to Requests for Proposals (RFPs) across three areas to support the development of PCORI's first Methodology Report. PCORI also issued RFPs for an analysis of the public input received on the working definition of "patient-centered outcomes research" and to conduct patient and caregiver focus groups to ensure the definition resonates with the ultimate beneficiaries of PCORI's work.

## Patient-Centered Outcomes Research Institute

### Management's Discussion and Analysis

---

PCORI RFPs are awarded through a competitive process. Calls for proposals are published on PCORI's website in the Funding Announcements section (<http://www.pcori.org/funding-opportunities/>) and distributed by email to PCORI's opt-in email list. Proposals that are submitted after an RFP are considered in a careful review process that includes:

- Excluding reviewers with a conflict-of-interest
- Scientific review by a small review committee that includes Methodology Committee members and Board members
- The opportunity for review by the full Methodology Committee
- A final decision by the Executive Director

The results of all funded projects, upon completion, are to be published on the PCORI website.

**Financial Highlights:** \$1.26 billion was appropriated for the Patient-Centered Outcomes Research Trust Fund (PCORTF) in 2010; \$10 million for fiscal year 2010, \$50 million for fiscal year 2011, and \$150 million a year for each of the eight years, 2012 through 2019. These amounts, less the annual 20% distribution to AHRQ and HHS beginning in 2011, are available to PCORI without further appropriation.

PCORI prepares annual financial statements in accordance with U.S. generally accepted accounting principles (GAAP), as issued by the Financial Accounting Standards Board. These statements are audited by independent auditors to ensure their integrity and reliability in assessing performance. The financial statements and notes are presented on a comparative basis.

The following table summarizes the significant changes in PCORI's financial condition during FY 2011:

Financial Condition	FY 2011	FY 2010	Increase	Percentage Difference
Assets	\$ 163,484,540	\$ 49,873,690	\$ 113,610,850	227.8%
Liabilities	\$ 2,513,990	\$ 315,339	\$ 2,198,651	697.2%
Net Assets	\$ 160,970,550	\$ 49,558,351	\$ 111,412,199	224.8%
Revenues	\$ 120,024,106	\$ 50,008,865	\$ 70,015,241	140.0%
Expenses	\$ 8,611,907	\$ 450,514	\$ 8,161,393	1811.6%

Below is a brief description of the nature of each required financial statement and its relevance. Certain significant balances or conditions are explained to elaborate on the impact on PCORI's operations. Readers are encouraged to gain a deeper understanding by reviewing PCORI's financial statements and notes to the accompanying financial statements.

**Statements of Financial Position:** The accompanying statement of financial position as of December 31, 2011, reports a change in unrestricted net assets of \$111,412,199. Specifically, PCORI's total assets of \$163,484,540 include cash of \$4,483,112. The total assets as of December 31, 2011, increased by \$113,610,850 from December 31, 2010, which is due to the receipt of appropriations. In addition, the increase in total assets reflects the purchase of property and equipment and an increase in prepaid deposits and expenses. PCORI moved its headquarters to a new location on March 30, 2012, and in preparation, PCORI started construction on the new leased space in 2011. The leasehold improvements are reflected in property and equipment, net.

Total liabilities reported are \$2,513,990 as of December 31, 2011, and they represent outstanding obligations. Total liabilities as of December 31, 2011, increased by \$2,198,651 from FY 2010.

## Patient-Centered Outcomes Research Institute

### Management's Discussion and Analysis

---

**Statements of Activities:** In FY 2011, support from appropriations totaled \$120,000,000. The program activities of \$4,439,114 are comprised of the program services of the Communications, Outreach, and Engagement, the Methodology, and the Research Committees. The combination of the revenue minus expenses yielded an excess of revenue over expenses totaling \$111,412,199. In FY 2010, support from appropriations totaled \$50,000,000. Expenses for program activities and support activities were \$620 and \$449,894, respectively, which resulted in revenue over expenses of \$49,558,351.

**Statements of Functional Expenses:** The \$4,438,494 increase in program services between FY 2011 and FY2010 is primarily due to the development of committees and the work product that resulted. In addition, the increase of \$3,722,899 in administrative and other support services includes an increase in salaries and Director's Compensation, as the Board of Governors began building out the infrastructure, the use of professional services to provide back office support, the development of contracting capacity, and an increase in the cost of daily operations.

**Future Events:** The PCORI senior management team is fully operational and will continue developing the organization's infrastructure to effectively manage daily operations and accomplish its mission.

**Request for Information:** This financial report is designed to provide a general overview of PCORI's finances. Questions concerning any of the information provided in this report, or requests for additional financial information, should be addressed to the Patient-Centered Outcomes Research Institute, 1828 L Street, NW, Suite 900, Washington, D.C. 20036. Additional information regarding PCORI's operations can be found at [www.pcori.org](http://www.pcori.org).

**Patient-Centered Outcomes Research Institute**

**Statements of Financial Position  
December 31, 2011 and 2010**

<b>Assets</b>	<b>2011</b>	<b>2010</b>
Cash	\$ 4,483,112	\$ 234,825
Amounts held by PCOR Trust Fund (Note 2)	158,078,971	49,638,865
Prepaid expenses and deposits	763,304	-
Property and equipment, net (Note 3)	159,153	-
	<b>\$ 163,484,540</b>	<b>\$ 49,873,690</b>
<b>Liabilities and Net Assets</b>		
Liabilities		
Accounts payable and accrued expenses	\$ 2,513,990	\$ 315,339
<b>Total liabilities</b>	<b>2,513,990</b>	<b>315,339</b>
Commitments and contingencies (Notes 2, 3, 4 and 5)		
Net assets		
Unrestricted	160,970,550	49,558,351
	<b>\$ 163,484,540</b>	<b>\$ 49,873,690</b>

The accompanying footnotes are an integral part of these statements.

**Patient-Centered Outcomes Research Institute**

**Statements of Activities**

**Year Ended December 31, 2011 and for the Period from November 10, 2010 (Inception)  
through December 31, 2010**

	<b>2011</b>	2010
Revenue and support:		
Federal appropriations	<b>\$ 120,000,000</b>	\$ 50,000,000
Interest income	<b>24,106</b>	8,865
<b>Total revenue and support</b>	<b>120,024,106</b>	50,008,865
Expenses:		
Program services:		
Communications, Outreach, and Engagement	<b>1,848,077</b>	620
Methodology	<b>1,410,127</b>	-
Research	<b>1,180,910</b>	-
Supporting services:		
Administrative – general	<b>3,166,048</b>	370,639
Administrative – board	<b>1,006,745</b>	79,255
<b>Total expenses</b>	<b>8,611,907</b>	450,514
<b>Change in net assets</b>	<b>111,412,199</b>	49,558,351
Net assets:		
Beginning	<b>49,558,351</b>	-
Ending	<b>\$ 160,970,550</b>	\$ 49,558,351

The accompanying footnotes are an integral part of these statements.

**Patient-Centered Outcomes Research Institute**

**Statements of Cash Flows**

**Year Ended December 31, 2011 and for the Period from November 10, 2010 (Inception) through December 31, 2010**

	<b>2011</b>	2010
Cash Flows From Operating Activities		
Change in net assets	<b>\$ 111,412,199</b>	\$ 49,558,351
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Changes in assets and liabilities:		
Increase in:		
Amounts held by PCOR Trust Fund	<b>(108,440,106)</b>	(49,638,865)
Prepaid expenses and deposits	<b>(763,304)</b>	-
Accounts payable and accrued expenses	<b>2,187,620</b>	315,339
<b>Net cash provided by operating activities</b>	<b>4,396,409</b>	234,825
Cash Flow From Investing Activities		
Purchases of property and equipment	<b>(148,122)</b>	-
<b>Net cash used in investing activities</b>	<b>(148,122)</b>	-
<b>Net increase in cash</b>	<b>4,248,287</b>	234,825
Cash:		
Beginning	<b>234,825</b>	-
Ending	<b>\$ 4,483,112</b>	\$ 234,825
Supplemental Schedule of Noncash Investing Activities		
Property and equipment included in accounts payable and accrued expenses	<b>\$ 11,031</b>	\$ -

The accompanying footnotes are an integral part of these statements.

**Patient-Centered Outcomes Research Institute**

**Statement of Functional Expenses  
Year Ended December 31, 2011**

	Program Services				Supporting Services			Total
	Communications, Outreach, and Engagement	Methodology	Research	Total Program Services	Administrative – General	Administrative – Board	Total Supporting Services	
Directors' compensation	\$ -	\$ 291,432	\$ -	\$ 291,432	\$ -	\$ 452,878	\$ 452,878	\$ 744,310
Salaries & wages – other	82,521	61,870	65,239	209,630	69,128	-	69,128	278,758
Other professional services	1,067,103	665,380	359,824	2,092,307	1,008,159	-	1,008,159	3,100,466
Management fees	479,979	130,967	682,794	1,293,740	479,331	-	479,331	1,773,071
Contracting capacity resources	-	-	-	-	986,500	-	986,500	986,500
Conferences, conventions, meetings	-	160,640	3,736	164,376	-	429,754	429,754	594,130
Travel	11,933	67,883	10,553	90,369	68,298	116,665	184,963	275,332
Legal fees	47,715	-	47,715	95,430	138,562	-	138,562	233,992
Employee benefits/payroll taxes	12,350	14,693	9,763	36,806	114,824	-	114,824	151,630
Rent, parking, other occupancy	-	-	-	-	145,082	-	145,082	145,082
Advertising	77,980	-	-	77,980	-	-	-	77,980
Focus groups	62,649	-	-	62,649	-	-	-	62,649
Accounting fees	-	-	-	-	55,705	-	55,705	55,705
Information technology	-	-	-	-	33,559	-	33,559	33,559
Insurance – non-employee related	-	-	-	-	14,725	833	15,558	15,558
Interim researchers	-	15,475	-	15,475	-	-	-	15,475
Equipment rental & maintenance	-	-	-	-	15,274	-	15,274	15,274
Telephone & telecommunications	1,587	1,720	1,199	4,506	5,956	4,375	10,331	14,837
Supplies	19	-	-	19	13,547	929	14,476	14,495
Books, subscriptions, references	3,850	67	87	4,004	5,591	-	5,591	9,595
Other expenses	-	-	-	-	5,164	-	5,164	5,164
Printing & copying	314	-	-	314	3,848	799	4,647	4,961
Bank/payroll fees	-	-	-	-	2,031	-	2,031	2,031
Postage & shipping	77	-	-	77	764	512	1,276	1,353
	\$ 1,848,077	\$ 1,410,127	\$ 1,180,910	\$ 4,439,114	\$ 3,166,048	\$ 1,006,745	\$ 4,172,793	\$ 8,611,907

The accompanying footnotes are an integral part of these statements.

Patient-Centered Outcomes Research Institute

Statement of Functional Expenses  
For the Period from November 10, 2010 (Inception) through December 31, 2010

	Program Services				Supporting Services			Total
	Communications, Outreach, and Engagement	Methodology	Research	Total Program Services	Administrative – General	Administrative – Board	Total Supporting Services	
Directors' compensation	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 78,049	\$ 78,049	\$ 78,049
Other professional services	-	-	-	-	72,928	-	72,928	72,928
Management fees	-	-	-	-	183,892	-	183,892	183,892
Conferences, conventions, meetings	-	-	-	-	19,486	409	19,895	19,895
Travel	-	-	-	-	10,617	516	11,133	11,133
Legal fees	-	-	-	-	71,624	-	71,624	71,624
Focus groups	420	-	-	420	-	-	-	420
Accounting fees	-	-	-	-	11,750	-	11,750	11,750
Information technology	200	-	-	200	-	-	-	200
Telephone & telecommunications	-	-	-	-	240	-	240	240
Supplies	-	-	-	-	69	31	100	100
Bank/payroll fees	-	-	-	-	33	-	33	33
Mailing services	-	-	-	-	-	250	250	250
	\$ 620	\$ -	\$ -	\$ 620	\$ 370,639	\$ 79,255	\$ 449,894	\$ 450,514

The accompanying footnotes are an integral part of these statements.

## Patient-Centered Outcomes Research Institute

### Notes to Financial Statements

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#### Note 1. Nature of Activities and Significant Accounting Policies

The Patient-Centered Outcomes Research Institute (PCORI) was established by federal law (42 U.S.C. 1301 et. seq.) and incorporated in November 2010 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.

PCORI is unique both in its mission and how it seeks to fulfill it. 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.

PCORI is a non-profit corporation, governed by a 21-member Board of Governors, including the Director of the Agency for Healthcare Research and Quality (AHRQ), the Director of the National Institutes of Health (NIH), and 19 members appointed by the Comptroller General of the United States. By law, the Comptroller must appoint three members representing patients and healthcare consumers, seven members representing physicians and providers, three members representing private payers, three members representing pharmaceutical, device, and diagnostic manufacturers or developers, one member representing quality improvement or independent health services researchers, and two members representing the federal government or the states (including at least one member representing a federal health program or agency).

In accordance with the enabling legislation, Congress has established the Patient-Centered Outcomes Research Trust Fund (PCORTF). The PCORTF received funding by a Congressional appropriation through 2019. Beginning in FY 2011, 20% of the amount funded is transferred in accordance with the enabling legislation to AHRQ and the Department of Health and Human Services (HHS). The remaining balance plus accrued interest represents the appropriations to PCORI. PCORI appropriations were \$120,000,000 and \$50,000,000 for fiscal years 2011 and 2010, respectively (See Note 2).

A summary of PCORI's significant accounting policies follows:

Basis of accounting: The accompanying financial statements are presented in accordance with the accrual basis of accounting, whereby, revenue is recognized when earned and expenses are recognized when incurred.

Basis of presentation: PCORI follows the accounting requirements of Financial Accounting Standards Board (FASB) Account Standards Codification (the Codification). As required by the Non-Profit Entities Topic of the Codification, PCORI is required to report information regarding its financial position and activities according to three classes of net assets: unrestricted, temporarily restricted, and permanently restricted. PCORI had no temporarily restricted or permanently restricted net assets at December 31, 2011 and 2010.

Property and equipment: Purchases of property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful life. It is the policy of PCORI to capitalize property and equipment purchases greater than \$500. Property and equipment at December 31, 2011, consisted of construction-in-process for tenant improvements. PCORI will amortize these costs over the term of PCORI's lease, which begins in fiscal year 2012.

## Patient-Centered Outcomes Research Institute

### Notes to Financial Statements

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#### Note 1. Nature of Activities and Significant Accounting Policies (Continued)

Valuation of long-lived assets: Long-lived assets and certain identifiable intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of long-lived assets is measured by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed of are reportable at the lower of the carrying amount or fair value, less costs to sell. At December 31, 2011 and 2010, management did not consider the value of any property or equipment to be impaired.

Revenue recognition: The PCORTF received its funding for 2010 through 2019 through an appropriation from Congress at the time of establishment. Federal appropriations are deemed to be earned and are recorded as revenue in the period designated by Congress. The government fiscal year ends on September 30.

Research awards: PCORI uses contracts as its only means of procurement for program services. Expenses are recorded at the time of the event, when the deliverable has been met or the cost has been incurred.

Tax status: PCORI, a non-profit organization incorporated in the District of Columbia and formed under the Patient Protection and Affordable Care Act, is exempt from income taxes under Section 501(c)(1) of the Internal Revenue Code (IRC). PCORI did not receive any revenue from any sources besides the PCORTF, and consequently, PCORI did not incur a federal or state income tax liability in 2011 or 2010.

PCORI follows the accounting standard on accounting for uncertainty in income taxes, which addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under this guidance, PCORI may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The guidance on accounting for uncertainty in income taxes also addresses de-recognition, classification, interest and penalties on income taxes, and accounting in interim periods. Management evaluated PCORI's tax positions and concluded that PCORI has not taken any uncertain tax positions that require adjustment to the financial statements to comply with the provisions of this guidance.

Functional allocation of expenses: The costs of providing various programs and activities have been summarized on a functional basis in the statements of activities. Accordingly, certain costs have been allocated among the programs and supporting services benefited.

Financial and credit risk: PCORTF was funded through Congressional appropriation in 2010, for the years 2010 through 2019. PCORI is the only organization that has the authority to draw from the PCORTF.

**Patient-Centered Outcomes Research Institute**

**Notes to Financial Statements**

**Note 1. Nature of Activities and Significant Accounting Policies (Continued)**

Use of estimates: The preparation of financial statements requires management to make estimates and assumptions in conformity with generally accepted accounting principles that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Subsequent events: PCORI evaluated subsequent events through April 20, 2012, which is the date the financial statements were available to be issued.

**Note 2. Amounts Held by PCOR Trust Fund**

Amounts held by PCOR Trust Fund at December 31, 2011 and 2010, are as follows:

	2011	2010
Beginning balance	\$ 49,638,865	\$ -
Federal appropriations:		-
Government Fiscal Year 2010 Appropriation	-	10,000,000
Government Fiscal Year 2011 Appropriation	-	50,000,000
Less AHRQ and HHS share 20% of appropriation as mandated by statute	-	(10,001,322)
Government Fiscal Year 2012 Appropriation	150,000,000	-
Less AHRQ and HHS share 20% of appropriation as mandated by statute	(30,000,000)	-
Interest earned	24,106	10,187
Less draws by PCORI	(11,584,000)	(370,000)
	<u>\$ 158,078,971</u>	<u>\$ 49,638,865</u>

PCORI receives its funding through appropriations from Congress. As such, the appropriations are subject to financial and compliance audits by the Government Accountability Office.

**Note 3. Property and Equipment**

Property and equipment and accumulated depreciation at December 31, 2011 and 2010, are as follows:

	2011	2010
Leasehold improvements	\$ 159,153	\$ -
Less accumulated depreciation	-	-
	<u>\$ 159,153</u>	<u>\$ -</u>

PCORI had no depreciation or amortization expense for the years ended December 31, 2011 or 2010. Leasehold improvements will be amortized over the life of the lease.

In December 2011, PCORI entered into an agreement with a construction company for the construction of its headquarters. The total value of the contract is \$1,015,076. PCORI has paid the construction company \$99,275 for the year ended December 31, 2011.

## Patient-Centered Outcomes Research Institute

### Notes to Financial Statements

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#### Note 4. Leases

During 2011, PCORI entered into a non-cancelable operating lease for office space in Washington, D.C., expiring on October 31, 2019.

Future minimum rental payments applicable to the lease at December 31, 2011, are as follows:

Years Ending December 31,

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2012	\$	648,814
2013		665,034
2014		681,658
2015		698,684
2016		716,113
2017 and thereafter		2,061,092
	\$	<u>5,471,395</u>

#### Note 5. Financial Risks and Uncertainties

The PCORTF was funded by appropriation of the U.S. Government through September 30, 2019. The potential for future changes to the enabling legislation exist, but the impact on the organization or the availability of funding is unknown at this time.



**Independent Auditor's Report on Internal Control over Financial Reporting  
and on Compliance and Other Matters Based on an Audit of Financial  
Statements Performed in Accordance With Government Auditing Standards**

To the Audit Committee  
Patient-Centered Outcomes Research Institute  
Washington, D.C.

We have audited the financial statements of Patient-Centered Outcomes Research Institute (PCORI) as of and for the year ended December 31, 2011, and have issued our report thereon dated April 20, 2012. We conducted our audit in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States.

Internal Control over Financial Reporting

Management of PCORI is responsible for establishing and maintaining effective internal control over financial reporting. In planning and performing our audit, we considered PCORI's internal control over financial reporting as a basis for designing our auditing procedures for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of PCORI's internal control over financial reporting. Accordingly, we do not express an opinion on the effectiveness of PCORI's internal control over financial reporting.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected, on a timely basis.

Our consideration of internal control over financial reporting was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control over financial reporting that might be deficiencies, significant deficiencies, or material weaknesses. We consider the following deficiency in internal control over financial reporting to be a material weakness, as defined above:

**Finding 2011-01: Financial Reporting**

*Questioned Costs:* None

*Condition and Context:* Federal appropriations are deemed to be earned and are recorded as revenue in the period appropriated by Congress. PCORI operates on a calendar fiscal year, while the appropriations from the federal government are made in accordance with the September 30 fiscal year of the government. PCORI recorded adjusting journal entries for fiscal years 2011 and 2010, to properly recognize the appropriation from the federal government as revenue and receivable from the PCOR Trust Fund, as well as the related investment earnings for those periods.

*Cause:* The timing difference between the two fiscal year-ends gave rise to the required adjustment.

*Effect:* The effect of the entries is to recognize \$40,000,000 and \$120,000,000 of revenue and related receivable from the PCOR Trust Fund for 2010 and 2011, respectively.

*Recommendation:* We recommend that management recognize revenue in accordance with the enabling legislation, and as such, revenue is recognized in the government fiscal year for which it was appropriated.

*Views of Responsible Officials and Planned Corrective Actions:* PCORI management agrees with this finding and has made all appropriate entries in the underlying financial statements and the revenue recognition protocol for future periods.

There has never been any confusion or disagreement regarding the nature of the PCOR Trust Fund (PCORTF) or the amount of funds contained in it; however, given the unique nature of PCORI, there has been some uncertainty regarding the timing of funding that is received by the PCORTF prior to the PCORI fiscal year and when these funds should be reflected in the PCORI financial statements.

In developing its accounting procedures, PCORI sought advice and counsel from legal, financial, and government accounting subject matter experts, and various government organizations with oversight and rule-making responsibilities. Based on this input, PCORI established a revenue recognition methodology that was challenged under audit, and PCORI agreed to make the requested change.

#### Compliance and Other Matters

As part of obtaining reasonable assurance about whether PCORI's financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the determination of financial statement amounts. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

PCORI's response to the finding identified in our audit is described in the finding noted above. We did not audit PCORI's response, and accordingly, we express no opinion on the response.

This report is intended solely for the information and use of the Audit Committee and management and is not intended to be and should not be used by anyone other than those specified parties.

*McGladrey & Pullen, LLP*

Vienna, Virginia  
April 20, 2012

## Patient-Centered Outcomes Research (PCOR) Definition

PCOR helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

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 potential benefits and harms of those options?"
3. "What can I do to improve the outcomes that are most important to me?"
4. "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

To answer these questions, PCOR:

1. Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision-making, highlighting comparisons and outcomes that matter to people;
2. 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;
3. Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
4. Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

*This definition includes many components of comparative effectiveness research but is intended to be broader to also include other focuses and other research methodologies.*



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