Building a Patient-Centered Research Community
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 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.
The Patient-Centered Outcomes Research Institute (PCORI) is authorized by Congress to conduct research to provide information about the best available evidence to help patients and their healthcare 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.

Our annual report features numerous quotes from patients and other stakeholders. All of the statements were made at PCORI’s fall 2012 engagement workshops.

“Patient-centered means patient-driven. It means the research we do is important to patients. It’s something that patients want done. It’s something that they need to know about because it will impact their lives.” —Patient
A Movement Has Begun

One year after PCORI’s Board of Governors was created, we wrote in the New England Journal of Medicine that this new research institute was “poised to lead a national movement that meaningfully involves patients and incorporates their voices in producing trusted, evidence-based information, promoting better decisions and ultimately better health for all.”

Today, we’re pleased to say that this movement is well under way and building real momentum. So we’re proud of our record of accomplishment that shows how the aspirations we expressed just over a year ago are that much closer to becoming a reality.

The movement we are privileged to nurture sits on a solid foundation of a maturing national research institute that we’ve been building from the ground up, as well as a growing community of patients, caregivers, researchers, clinicians, policymakers and other healthcare stakeholders who are increasingly invested in our work. This community has helped us develop our road map and standards for trustworthy, useful and patient-centered comparative clinical effectiveness research. It has helped us launch and continue to refine a rigorous approach to soliciting, assessing and funding promising research proposals that meaningfully takes account of the patient’s voice.

This report details the substantial progress we made in 2012 toward meeting the bold goals set out for us in our authorizing legislation, the Patient Protection and Affordable Care Act of 2010. But even as we celebrate what we’ve achieved, we know that we have far more to do.

We enter 2013 with a clear sense of some of those next steps, guided by three strategic goals:

- Substantially increase the quantity, quality and timeliness of useful, trustworthy information to support decision making.
- Speed the implementation of patient-centered knowledge into practice.
- Influence clinical and healthcare research funded by others to be more patient-centered.

We know solid research takes time, especially if it is to be developed through new and challenging approaches that aim to both improve patient outcomes and have a meaningful real-world impact. But we’re confident of substantial progress in the coming year.

Our operations continue to grow in size and sophistication. We look forward to involving more patients and other stakeholders in our work through the establishment of PCORI Advisory Panels and ongoing engagement events, both live and virtual. We expect to substantially increase our levels of research funding in the coming year through new and targeted funding announcements. And we plan a robust effort to introduce our methods standards to audiences across the healthcare community in an effort to encourage them to make this work their own, refine it, improve it and apply it.

Thank you for your interest in and support of PCORI during the past year. We look forward to continue working with you in the coming year to see that patients and those who care for them have the information they need to answer the questions that matter most to them.

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’re proud of our record of accomplishment that shows how the aspirations we expressed just over a year ago are that much closer to becoming a reality.”

— Eugene Washington and Steven Lipstein
The Year of Engagement

As we look back at PCORI’s many achievements in 2012, one theme emerges clearly. This was the “year of engagement,” as we pursued a robust, multi-pronged effort to bring patients and other stakeholders from across the broader healthcare community fully into our efforts to advance patient-centered comparative effectiveness research.

There are many examples of how we sought to make this commitment real. We convened thousands of stakeholders through live and online workshops, roundtables and webinars. We actively sought public input in establishing our national research priorities and research agenda as well as on the methodology standards we hope will guide rigorous patient-centered outcomes research in the future. We established an initial set of multi-stakeholder advisory panels to help guide the work carried out under our funding priorities.

Bringing together all stakeholders in the healthcare enterprise to set research priorities, with patients at the center, is our formula for ensuring that we fund and conduct the most relevant research possible. We've asked stakeholders from across the healthcare community to serve as reviewers of our funding proposals and to suggest the critical patient-centered research questions that those proposals should try to answer. We launched a “challenge” initiative seeking broad community expertise in helping us to connect patients and researchers as partners in developing and conducting the studies we support.

And we put money behind our principles. We committed $31 million in PCORI Pilot Project awards for studies designed to better define key underlying methodological questions that will advance patient-centered outcomes research. We also approved another $41 million in our first round of primary research funding for projects that, in addition to adhering to the highest standards of scientific rigor, met our criteria for patient-centeredness, likely impact on practice, and meaningful inclusion of patients and other stakeholders in all aspects of the research process.

These activities, and many more that we plan in 2013, add up to the base upon which we are building a robust patient-centered research community, a growing assembly of patients, caregivers, researchers, policymakers and others who are becoming committed participants in guiding our work.

We are continually impressed by the enthusiasm, passion and wisdom of this growing community. But we know that for all the progress we've made in the past year, tremendous challenges remain if we are to establish a portfolio of patient-centered research that can demonstrate the value, utility and impact to our stakeholders that they—and we—expect.

So we look forward to building upon our “year of engagement” with a year of strategic investment in rigorous research guided by the voices of patients and other stakeholders. We plan to commit up to $350 million to that research in the coming year, remaining focused on ensuring that the studies we fund address the questions and concerns that matter most to patients and those who care for them.

Thank you for your interest in and support of PCORI. We look forward to continuing our work with you.

Joe V. Selby, M.D., M.P.H.
Executive Director

Anne C. Beal, M.D., M.P.H.
Chief Operating Officer

“Bringing together all stakeholders in the healthcare enterprise to set research priorities, with patients at the center, is our formula for ensuring that we fund and conduct the most relevant research possible.”

—Joe Selby and Anne Beal
STEADY PROGRESS ON THE PATH TO PATIENT-CENTERED RESEARCH

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by the Patient Protection and Affordable Care Act of 2010 to “assist patients, clinicians, purchasers, and policymakers in making informed health decisions” by producing high-quality and highly useful comparative effectiveness research (CER).

Our work will provide patients, those who care for them, and the broader healthcare community, with a greater understanding of the prevention, diagnosis and treatment options available to them and the science that supports these choices. As we build this portfolio of research, we are guided by ongoing and systematic engagement with our stakeholders, along with funding and review criteria that are uniquely patient-centered while maintaining the highest standards of scientific rigor. We call this approach “research done differently.”

We spent the first year after our creation crafting the initial infrastructure needed to build a major national health research institute from the ground up. As a result, we entered 2012 well positioned to pursue an ambitious agenda that resulted in our meeting a significant number of milestones, including critical foundational activities mandated by law.

PCORI’s MAJOR 2012 ACCOMPLISHMENTS

- Adopting a guiding definition of Patient-Centered Outcomes Research (PCOR)
- Approving our first National Priorities for Research and Research Agenda
- Adopting Methodology Standards for patient-centered CER
- Issuing $31 million in PCORI Pilot Projects
- Issuing our first PCORI Funding Announcements (PFAs) and $41 million in resulting first-round primary research
- Pursuing a robust program to engage patients, caregivers, researchers, clinicians, payers, industry and other healthcare stakeholders in all aspects of our work

This report details these and other activities that we undertook during what was a year of substantial progress in continuing to build a new national research institute, starting to fund useful, impactful CER projects, and ensuring that the voices of patients and other stakeholders are meaningfully reflected throughout the process. We are pleased to quote many of those voices in the pages that follow.

PCORI 2012 Timeline

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<thead>
<tr>
<th>JANUARY</th>
<th>FEBRUARY</th>
<th>MARCH</th>
<th>APRIL</th>
<th>MAY</th>
<th>JUNE</th>
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<tr>
<td>- Board meeting, Jacksonville, FL</td>
<td>National Patient and Stakeholder Dialogue</td>
<td>Board meeting, Baltimore, MD</td>
<td>Board reviews public comments and proposed revisions to draft National Priorities and Research Agenda</td>
<td>Board meeting, Denver, CO</td>
<td>Special Board webinar on Conflict of Interest policy</td>
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<td>- Awards contracts to review guidance documents for selecting PCOR methods</td>
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<td>Begins analysis of public comment on draft National Priorities and Research Agenda</td>
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<td>First draft Methodology Report delivered to Board</td>
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<td>- Releases draft National Priorities and initial Research Agenda for public comment</td>
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<td>Board reviews and adopts revised National Priorities for Research and Research Agenda</td>
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<td></td>
<td>Board approves Pilot Projects</td>
<td></td>
<td>Broad PCORI Funding Announcements (PFAs) issued under first four priorities</td>
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An Expanding and Evolving Research Organization

We focused in 2012 on solidifying and enhancing the infrastructure, policies and procedures needed for PCORI to function effectively; carrying out a series of foundational and organizational tasks mandated by our authorizing legislation; starting to build a broad-based portfolio of patient-centered CER; and continuing to develop the community of engaged healthcare stakeholders essential to the conduct, refinement and eventual dissemination and implementation of the results of that work.

These efforts were directed by our 21-member multi-stakeholder Board of Governors and managed by a professional staff committed to building our research portfolio while ensuring the effective participation throughout the process of key healthcare constituencies. We had a total of 47 programmatic and support staff as of the end of the year, including full-time or acting directors for four of our five scientific program areas and directors of patient and stakeholder engagement, engagement research, communications, contracts management, finance, human resources and information technology.

Defining Patient-Centered Outcomes Research (PCOR)

In March, the Board adopted a revised draft of a document defining “patient-centered outcomes research (PCOR),” a concept that had been defined in a number of different ways within professional circles at the time PCORI was established. Such a definition was one of our foundational tasks, designed to help clarify our focus and scope of work. A draft definition was developed through a year-long iterative and transparent process that included a public comment period that generated feedback from nearly 120 organizations and 450 individuals. We solicited additional public input through six focus groups involving patients, caregivers and the general public.

PCORI’s Research Roadmap

In May, our Board adopted our legislatively mandated research roadmap, our National Priorities for Research and Research Agenda. A draft version, development of which began in August 2011, was released in January 2012 for a 53-day public comment period and revised based on the approximately 450 comments received. We solicited public comment through a range of activities, including a national dialogue event in Washington, DC, that attracted...
800 people both in person and via webcast, along with numerous small-group meetings with stakeholders, extensive online outreach and digital advertising.

PCORI’s NATIONAL PRIORITIES FOR RESEARCH AND RESEARCH AGENDA

- Assessment of Prevention, Diagnosis and Treatment Options
  - Comparisons of alternative clinical options to support personalized decision-making and self-care
  - Identifying patient differences in response to therapy
  - Studies of patient preferences for various outcomes

- Improving Healthcare Systems
  - Improving support of patient self-management
  - Focusing on coordination of care for complex conditions and improving access to care
  - Comparing alternative strategies for workforce deployment

- Communication and Dissemination Research
  - Understanding and enhancing shared decision-making
  - Alternative strategies for dissemination of evidence
  - Exploring opportunities to improve patient health literacy

- Addressing Disparities
  - Understanding differences in effectiveness across groups
  - Understanding differences in preferences across groups
  - Reducing disparities through use of findings from PCOR

- Accelerating PCOR and Methodological Research
  - Improving study designs and analytic methods of PCOR
  - Building and improving clinical data networks
  - Methods for training researchers and patients to participate in PCOR
  - Establishing methodology for the study of rare diseases

These priorities were written to be intentionally broad and did not name specific conditions or treatments for study. This approach recognized that there are many important research questions that PCORI could answer and that focusing on a narrow set of conditions at the start of our research funding would exclude certain patients at a very early stage in our work. However, even as our Priorities and Agenda were finalized, we began mapping out a process for identifying specific topics for funding, following a complementary two-path process that included both proposals initiated by the research community and those initiated by patients and other stakeholders. We detail this approach on page 7.

An Evolving Strategic Plan

To further guide our activities, we worked closely with our Board during 2012 to develop our strategic plan, outlining a set of strategic imperatives, or pillars: Engagement; Methods; Research; Dissemination; and Infrastructure. These imperatives support PCORI’s three overarching goals:

PCORI’s STRATEGIC GOALS

- Substantially increase the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence clinical and health care research funded by others to be more patient-centered

As the year ended, PCORI staff were working to flesh out the strategies for attaining these goals, developing metrics and milestones for accountability and performance management, and identifying priorities for 2013. A full draft of the strategic plan was being prepared for Board discussions and approval in 2013.

“How do we give the people the right information so that they can make those choices themselves? That should be the goal of research … It should help the patient or the stakeholder to make an informed decision.” —Insurance industry researcher
A ROBUST AND RIGOROUS RESEARCH PROGRAM

Multiple Research Paths and Milestones
We took several key steps in 2012 toward building a robust portfolio of research that will provide patients and those who care for them with the information they need to make better-informed health and healthcare decisions. Most notably, we began fulfilling our core function of funding patient-centered CER by approving more than $70 million in research contracts through our first two major funding releases—our Pilot Projects program and the first round of our primary research awards.

We follow a complementary two-path approach in building our portfolio of high-impact research guided by our National Priorities for Research and Research Agenda. The PCORI Funding Announcements (PFAs) resulting from this process are designed to address questions of greatest concern to patients, caregivers, clinicians and other healthcare stakeholders.

We started down the first of these paths in May 2012 with the release of PFAs under our first four national priorities; the first in a series of PFAs under the fifth priority was released in November. These broad announcements count on the research community to submit proposals to pursue studies on critical investigator-initiated topics. A strict set of application guidelines and application review criteria assure that the proposals we consider not only meet our legislative mandate but remain patient-centered and focused on likely impact on practice. In December 2012, we announced the successful applicants for this first funding cycle (see page 10). Moving into 2013, PCORI will be accepting applications in response to these announcements every four months.

<table>
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<tr>
<th>TWO PATHS TO RESEARCH FUNDING</th>
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<tr>
<td><strong>INVESTIGATOR-INITIATED</strong></td>
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<tr>
<td><strong>PATIENT/OTHER STAKEHOLDER-INITIATED</strong></td>
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“PCORI has a unique opportunity to get answers to the questions that haven’t been asked so far, or haven’t been asked in a way that patients are getting what they want out of the research.” — Pharmaceutical industry representative

PCORI’s Initial Review Criteria

1. Impact of the Condition on the Health of Individuals and Populations
2. Potential for Improving Care and Outcomes
3. Effects on Healthcare Delivery
4. Patient-Centeredness
5. Rigorous Research Methods
6. Inclusiveness of Different Populations
7. Research Team—Engagement
8. Efficient Use of Research Resources

We also set the groundwork in 2012 for a second path to future funding opportunities that will add greater specificity to our research portfolio. With the help of our Methodology Committee, other scientific experts, patients and other stakeholders, our staff began developing a topic generation and research prioritization process to complement the broad PFAs. This process will identify high-priority research questions that eventually could be developed into funding announcements. This process is designed to generate research topics that directly reflect patients’ questions, soliciting such questions through our website and engagement activities. By the end of the year, we had collected more than 600 such questions through this approach, piloted a process for prioritizing them, and established an initial set of multi-stakeholder PCORI Advisory Panels to assist our staff in assessing them for eventual Board consideration, as well as to advise on our patient engagement efforts generally.

TOPICS CONSIDERED FOR PCORI’s FIRST TARGETED FUNDING ANNOUNCEMENTS

- Treatment Options for Uterine Fibroids
- Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos
- Preventing Injuries from Falls in the Elderly
- Treatment Options for Back Pain
- Obesity Treatment Options in Diverse Populations

Anticipating that this approach would take some time to produce funding announcements, and mindful of stakeholder feedback to move rapidly toward targeted funding, we decided to jump-start the process. Using previous stakeholder-vetted efforts to identify critical CER questions, including those undertaken by the Institute of Medicine, Agency for Healthcare Research and Quality, National Institutes of Health, American Nurses Association and the Friends of Cancer, we identified five high-impact topics for potential development into funding announcements. We established a series of ad hoc multi-stakeholder work groups to help us define specific research questions to be studied in each topic, with a goal of issuing funding announcements by mid-2013.

PCORI’s Pilot Projects

In April, our Board approved a slate of 50 PCORI Pilot Projects awards, funding $31 million in research, in 24 states and the District of Columbia, over two years. We developed the program to support projects in eight
areas of interest focused on new methods for advancing patient-centered outcomes research and particularly on engaging patients in the research process.

We issued a request for applications promoting observational methodologies, systematic reviews, mixed methods and qualitative methodologies, simulations, small pragmatic pilot trials, and survey methods to address eight specific focus areas. These included methods for engaging patients in identifying research gaps, prioritizing research topics, advancing analytical methods for CER, developing patient-centered research methods and patient-oriented outcomes instruments, collaborating with stakeholders in building research teams, patient-provider communication, and translating evidence into practice.

The request generated nearly 1,400 letters of intent and nearly 850 applications. Merit reviews took place in the first quarter of 2012, and on May 22, PCORI’s Board of Governors approved 50 proposals for funding. To optimize opportunities to learn from and broadly apply the lessons learned from these projects, we contracted with AcademyHealth to help identify common themes across the pilot projects, to convene investigators with related projects and to synthesize lessons related to engagement of patients from the 50 projects.

Our First Round of Primary Research Funding

As noted earlier, we issued our first calls for primary research proposals in May. In addition to supporting research that will yield valuable evidence, these funding opportunities were the first to demonstrate our unique and demanding patient-centered research criteria.

Applicants had to show that they planned to meaningfully engage patients and other stakeholders while maintaining scientific rigor. To further ensure the inclusion of all perspectives, the projects were selected through a competitive, multi-stage review process that incorporated patients, caregivers and other stakeholders in the evaluation of proposals.

Future funding opportunities will benefit from the lessons that we, researchers and stakeholders all learn from these initial experiences. We expect future rounds of funding will attract an even larger pool of high-quality applications.
We received 483 applications under the first cycle of our round of funding. After a two-stage review involving more than 100 scientists, patients and other stakeholders, our Board, on December 18, approved a slate of 25 projects in 17 states totaling nearly $40.7 million in funding over three years. A second funding cycle under the first four National Priorities for Research opened in September; we received 434 applications for that round. Successful applicants will be notified in May 2013.

The PCORI Challenge
As part of this effort to support this focus, we launched a “challenge initiative” late in the year using a “crowd-sourcing” model to seek proposals for creating a “matching service” to connect researchers and patients as prospective research partners. This was designed to support our funding requirement that patients and caregivers play a meaningful collaborative role throughout the research process. The solution could be a well-articulated conceptual model, an adaptation of an existing matching protocol, a prototype for new web-based service or app, or some combination of these.

We offered two cash prizes to the winning innovators, one ($10,000) for a conceptual model and another ($40,000) for a prototype. We planned to empanel a team of judges, including patients, patient advocates, researchers, technologists and others, to review the proposals. Winners will be announced in the spring of 2013.

Additional Research Supported in 2012
In addition to funding through our Pilot Projects Program and PFAs, we awarded a series of research contracts through a competitive Request for Proposal (RFP) process. Those included:

- Pilot Projects Monitoring Services
- Results Analysis Services
- Survey Research Services
- Review of Guidance Documents for Selected Methods in Patient-Centered Outcomes Research

Details on these and other awarded contracts may be found on pages A1–A5 of the Appendix.
Setting Standards for Patient-Centered CER

PCORI was established not only to enhance the volume of research available to patients and those who care for them, but to create widely accepted standards for how this research should be conducted. We know that patients can suffer when the information they rely upon to make decisions is not reliable or does not address important questions about their care.

To improve the quality of information healthcare research produces, our 17-member Methodology Committee began working in 2011 to develop an initial set of clear, rigorous standards for patient-centered CER, along with a translation table and set of research recommendations to be used as tools for guiding our Board in overseeing our research agenda.

This process was rigorous in its own right. The Committee established four working groups, on Patient-Centeredness, Research Priorities, Research Methods, and Report Assimilation, to assist in the effort. The Committee also relied on input from leading methodologists from around the country and a set of expert background reports to ensure that PCORI’s methods standards would be closely aligned with scientific evidence and best practices.

The Committee submitted the draft standards to our Board in May, as required by law, along with a report putting the standards in context and a set of research recommendations. We released the draft in July for a 54-day public comment period, receiving more than 1,200 specific comments from 124 individual and organizational stakeholders. In November, our Board adopted 47 revised standards. The process of revising the accompanying report was expected to be completed in the spring of 2013.

PCORI’s Initial Methodology Standards

- Patient-Centeredness
- Formulating Research Questions
- Systematic Reviews
- Crosscutting Methods for PCOR
- Causal Inference
- Heterogeneity of Treatment Effect
- Preventing and Handling Missing Data
- Data Networks
- Adaptive and Bayesian Trial Designs
- Data Registries
- Studies of Diagnostic Tests

The process of developing, refining and finalizing these standards marks an enormous achievement and a critical step in advancing the field of patient-centered outcomes research. The standards set a high bar for patient-centeredness and scientific rigor, and PCORI expects that the future funding proposals we receive will adhere to those standards.

Our goal is for the standards and recommendations we put forth to become universally adopted by the research community. With that objective in mind, we are continually consulting with researchers and stakeholders to address any questions or concerns that arise. With their support, PCORI can succeed in helping healthcare research contribute evidence that is more responsive to patient and caregiver needs, and more likely to support quality outcomes.

“If medical research is to realize the promise of improving health, getting the methods right matters.”—Sherine Gabriel, M.D., Dean, Mayo Medical School, and Chair, PCORI Methodology Committee
Focusing on “End Users”
PCORI was founded on the premise that more and more meaningful involvement in CER by the entire healthcare community will produce trusted, authoritative and relevant answers to the real-word questions patients and other healthcare decision-makers face every day. This is not “engagement for engagement’s sake” but rather as a path to rigorous, robust and salient research. We believe this approach ultimately will improve the quality of care—especially in the high-burden, high-impact conditions, and among the particular populations, our authorizing legislation tells us to address.

This focus on engagement has been a core commitment and guiding principle virtually since the institute’s creation and is memorialized in the mission statement adopted by the Board 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.”

In 2012, building on the work of others, such as the Agency for Healthcare Research and Quality (AHRQ), the Food and Drug Administration and the National Institutes of Health, we used a number of mechanisms to more closely engage the “end users” of our work in the research process itself. This included channels for members of the healthcare community to help define and refine the research questions that form the basis of the studies we fund, reviewing the research applications we receive, serving as members of the research teams we support, and playing a role in the process of disseminating the study results.

As noted earlier, we put these principles into practice through the criteria that drive our work. Among the most visible examples of this approach are our requirements for patient-centeredness and meaningful involvement by patients and other stakeholders on the research team, as well as having patients and other healthcare stakeholders to the table to review research applications. Our review process asks patients, caregivers and other non-scientific reviewers to focus on these three criteria:

### KEY CRITERIA

<table>
<thead>
<tr>
<th>Potential for Improving Care and Outcomes:</th>
<th>Might the proposed research lead to meaningful improvement in patient health and is the approach novel or innovative in ways that make it likely to change practice?</th>
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<tr>
<td>Patient-Centeredness:</td>
<td>Is the proposed research focused on questions and outcomes of specific interest to patients and their caregivers?</td>
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<tr>
<td>Research Team—Engagement:</td>
<td>Do the researchers have appropriate experience and have they included in their team the relevant patients and other key healthcare community members who are the focus of the study and would use its information?</td>
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Building a Patient-Centered Research Community
In 2012, we used live convening and a range of online tools to seek a broad array of stakeholder input on our work, attracting thousands of patients, caregivers, researchers, clinicians, advocacy groups and other stakeholders. These events served to begin and maintain a robust dialogue with patients, caregivers, patient advocates, clinicians, nurses, researchers, payers, employers, policymakers, industry and other stakeholder groups to advance our patient-centered research agenda.

Our open bimonthly Board meetings featured public comment periods and were webcast. Our Methodology
“Initially, I was a little intimidated by being side-by-side with scientific stakeholders, but I also felt like my input was valuable to the panel. ... Everyone wanted to hear my thoughts and they appreciated what the patients were bringing to the panel, because our experiences are obviously so different than scientists.”—Patient advocate

Committee met with patients, caregivers, and dozens of clinical, research and patient advocacy organizations in the course of its work. More than a dozen workshops, roundtables and other gatherings facilitated our ongoing dialogue with stakeholders as we pursued our work, including as we developed and refined our National Priorities for Research and Research Agenda, methods standards, and advanced our process for identifying and prioritizing specific research topics to study.

We held five workshops to develop new opportunities for collaboration between patients, researchers and others within the healthcare community. These events, and additional meetings we plan in 2013, were designed to foster development of the network of engaged stakeholders that will provide critical guidance for our patient-centered research agenda.

In February, we convened hundreds of stakeholders in person and online to tell us what they want and need our research to accomplish. In July, we assembled a multi-stakeholder group of experts to discuss how we can facilitate the creation of a national data infrastructure to support high-quality PCOR. In October, we brought together nearly 150 stakeholders to work with us to start building a patient-centered research community. And we held two workshops back-to-back in December to further engage the community in our process for selecting and prioritizing the topics we hope to see researchers study in the near future.

Supporting outreach and communications about these events, we substantially grew our online and social media presence throughout the year. Key website traffic metrics increased 56% during the year, our opt-in email list recorded a 370% increase and we saw a nearly 10-fold jump in Twitter followers. These channels kept our audiences updated on our events, funding opportunities and ways to provide meaningful input about our work, as well as supporting efforts to seek applicants for our growing pool of application reviewers and soliciting research questions for our science team to consider for funding announcements.

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<tr>
<th>MAJOR ENGAGEMENT EVENTS</th>
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<td>February 27: National Patient and Stakeholder Dialogue</td>
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<td>July 2–3: National Workshop to Advance Use of Electronic Data</td>
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<td>August 30: Disabilities Roundtable</td>
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<td>October 27–28: Patient Engagement Workshop</td>
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<td>December 4: Stakeholder Engagement Workshop</td>
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<td>December 5: Methodology Workshop for Prioritizing Specific Research Topics</td>
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Celebrating PCORI-Funded Research

PCORI has developed a series of feature stories celebrating our patient-centered research enterprise and its unique contributions to clinical care in addressing questions faced by patients and other healthcare decision makers. The stories are distributed nationally and appear in a variety of print, broadcast and online publications. The series is part of our broad communications and engagement effort to let all interested patients and healthcare stakeholders know about our expanding work and the opportunities for participation.

Transforming Health Research on the High Plains

Yuma, Colorado—Ned Norman is a rancher. Maret Felzien is an English professor. And conventional wisdom says neither is likely to help healthcare research become more meaningful to patients and caregivers.

But Norman and Felzien, and their rural community in eastern Colorado, are doing just that through the High Plains Research Network (HPRN), a partnership of rural hospitals, clinics and primary care practices that are improving the care they provide to patients through research and quality improvement programs.

The network is one example of the Patient-Centered Outcomes Research Institute’s (PCORI) vision for research that meaningfully engages members of the community. That’s why PCORI (www.pcori.org) awarded the HPRN a Pilot Project contract in April 2012 to continue its community-based effort through “Boot Camp Translation.”

Led by HPRN Director Dr. Jack Westfall, the project will translate health research and recommendations into language accessible to the diverse communities in Colorado. The ultimate goal is to increase the awareness and use of evidence-based recommendations and improve patient health.

“We speak for the community,” Felzien said. “And when you pair our energy and our knowledge with research, the health of our community can be improved.”

The traditional healthcare research model excludes patients and community members not because of poor intentions, but from the lack of proven methods for community engagement. The HPRN is demonstrating a new model that can be adapted and utilized in communities nationwide.

“My vision for our research endeavor is to build a community of solutions… patients, community members, providers, researchers, all working together to ask and answer questions important to the community,” Westfall said.

That’s PCORI’s vision as well, with the hope that efforts like the HPRN can become proven models for “research done differently.” PCORI encourages people to visit www.pcori.org/get-involved to see how they can help.
We look back at 2012 as a year of significant progress in establishing the foundation needed to make major strides in funding patient-centered CER and starting to develop a robust research portfolio. We entered 2013 focused on building on this base to strategically invest up to the $355 million we have available to support additional projects through multiple funding cycles across our priority areas.

We will continue to seek proposals under our original broad funding announcements but focus greater attention on our efforts to develop and issue more targeted calls for research proposals. We will start mid-year with the topic areas approved by our Board in late 2012 and expand this focused funding effort later in 2013 as our research prioritization and advisory panel processes produce multiple PFAs.

As we move ahead with our funding, our selection criteria for all proposals will remain tightly focused on our patient-centered mission and commitment to support studies that have real-world impact. Research contracts will be awarded only to projects that hold the promise of changing practice, effectively engage patients, caregivers and others across the healthcare community in all aspects of the research process, and address questions that matter to patients.

We’re confident that this distinctive approach will produce research findings that will meaningfully improve patient outcomes, but we know these requirements mean some researchers will have to adjust the way they think about their work in seeking funding from us. We’re keen on working with the entire research community—seasoned professionals, new investigators and the stakeholders with whom they will partner—to help everyone better understand our goals and unique funding criteria.

The coming year also will be one where we place increasing emphasis on one of the other core responsibilities outlined in our authorizing legislation—dissemination of our research findings. After all, producing trustworthy and useful patient-centered CER takes time to do well, but that time is wasted unless the results are widely used and lead to more effective care. That’s one outcome we take especially seriously.

We’ll begin by seeking to promote adherence to, and ongoing refinement of, the initial set of patient-centered outcomes research standards drafted by our Methodology Committee and adopted by our Board. Because we know that mere publication of these standards won’t change practice, we need to seek the active participation and help of the entire healthcare community in this effort. Throughout the year, therefore, we’ll focus on building the networks and communities of researchers, clinicians, industry representatives and other key stakeholders who we hope will make these standards their own, improve them over time and incorporate them routinely into professional practice.
We plan to leverage these same outreach and engagement efforts to set the stage for dissemination—and, we hope, eventual implementation—of our primary research results as they become available. We plan to work closely with AHRQ, our legislatively mandated dissemination partner, in these efforts.

If our list of 2013 resolutions is long and ambitious, it’s because we understand the urgency felt by patients, those who care for them and the healthcare community broadly to have access to better information to support clinical decisions. PCORI was created to help fill the gap in our understanding of which prevention, treatment and care options will result in the best outcomes for patients and, in so doing, improve the health and healthcare experience of millions of Americans.

The key to our success in 2013 and beyond is the same as it has been since we were established—our ability to solicit and incorporate perspectives from the entire healthcare community as we advance and refine our work.

Our growth and accomplishments in 2012 are a direct reflection of that support, which is why we are so optimistic about the coming year. We are very pleased with the level of commitment, energy and passion the public has displayed in its interaction with PCORI, whether at our Board meetings, workshops, in formal public comments, routine e-mail messages, blog posts or Twitter discussions.

We are excited to continue working toward our shared goal of improving patient outcomes through scientifically rigorous, patient-centered research in 2013.

“We are why research is done. We all want to do meaningful research that furthers the conversation and improves health outcomes. What I see as the benefit is we start having more transparent research, we have higher quality research and that research results actually have the impact they were meant to have.”—Patient/patient advocate
The Patient-Centered Outcomes Research Institute is funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF). At the beginning of the federal government fiscal year (October 1, 2012 to September 30, 2013), the PCORTF received $150 million in federal appropriation and $52 million in transfers from the Federal Hospital Insurance (FHI) and the Federal Supplementary Medical Insurance (FSMI) Trust Funds. The Treasury department transferred 20% of the these funds 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 (CER).

PCORI’s mission is to use these funds to “assist patients, clinicians, purchasers, and policymakers in making informed health decisions” by producing high-quality and highly useful CER. This report has provided many of the details of what PCORI undertook during 2012 in continuing to build this new national research institute with the express objective of accomplishing its mission as defined in the Patient Protection and Affordable Care Act of 2010. The following table summarizes the 2012 activities presented in this report.

- Solidified and enhanced infrastructure
- Adopted guiding definition of Patient-Centered Outcomes Research (PCOR)
- Adopted legislatively mandated research roadmap: National Priorities for Research and Research Agenda
- Evolved strategic plan
- Building robust and rigorous portfolio of research
- Established multi-stakeholder PCORI Advisory Panels
- Issued Targeted Funding Announcements
- Awarded $31 million in Pilot Research Projects
- Issued First Round of Primary Research Funding
- Issued PCORI challenge to connect researchers and patients
- Set standards for Patient-Centered CER
- Building a patient-centered research community using a range of tools

### FINANCIAL HIGHLIGHTS

A Year of Substantial Progress in Continuing to Build A New National Research Institute

The Patient-Centered Outcomes Research Institute is funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF). At the beginning of the federal government fiscal year (October 1, 2012 to September 30, 2013), the PCORTF received $150 million in federal appropriation and $52 million in transfers from the Federal Hospital Insurance (FHI) and the Federal Supplementary Medical Insurance (FSMI) Trust Funds. The Treasury department transferred 20% of the these funds 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 (CER).

PCORI’s mission is to use these funds to “assist patients, clinicians, purchasers, and policymakers in making informed health decisions” by producing high-quality and highly useful CER. This report has provided many of the details of what PCORI undertook during 2012 in continuing to build this new national research institute with the express objective of accomplishing its mission as defined in the Patient Protection and Affordable Care Act of 2010. The following table summarizes the 2012 activities presented in this report.

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- Building a patient-centered research community using a range of tools

### FUNCTIONAL EXPENSES

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### STATEMENT OF ACTIVITIES

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Board of Governors

Debra Barksdale, PhD, RN
Kerry Barnett, JD
Lawrence Becker
Carolyn M. Clancy, MD
Francis S. Collins, MD, PhD
Allen Douma, MD
Arnold Epstein, MD
Christine Goertz, DC, PhD
Leah Hole-Marshall, JD
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
Eugene Washington, MD, MSc (Chair)
Harlan Weisman, MD
Robert Zwolak, MD, PhD

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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

Committee as of Dec. 31, 2012.

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, DSc
Jean R. Slutsky, PA, MSPH
Clyde Yancy, MD, MSc

Research Methods Working Group
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Robin Newhouse, PhD, RN (Co-Chair)
Michael S. Lauer, MD
Sharon-Lise Normand, PhD
Sebastian Schneeweiss, MD, ScD

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

These Methodology Committee Working Groups supported the development of PCORI’s draft methodology report and methodology standards and completed their work in 2012.

Special Committees

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

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Alfred O. Berg, MD, MPH
Mark Helfand, MD, MPH, MS
Harlan Krumholz, MD
Michael S. Lauer, MD
Joe Selby, MD, MPH

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Sherine Gabriel, MD, MSc, PCORI Member
Art Levin, MPH, Consumer Advocate, Center for Medical Consumers
Bernard Lo, MD, Ethicist, UC San Francisco—Professor Emeritus
Gail Shearer, MPP, Senior Advisor, PCORI
Robert Zwolak, MD, PhD, PCORI Board Member

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Carolyn M. Clancy, MD
Arnold Epstein, MD
Sherine Gabriel, MD, MSc
Christine Goertz, DC, PhD (Advisor, non-voting)
Gail Hunt
Steve Lipstein, MHA
Joe Selby, MD, MPH
Clyde Yancy, MD, MSc

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Freda Lewis-Hall, MD
Robert Zwolak, MD, PhD

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Gail Hunt
Robert Jesse, MD, PhD
Grayson Norquist, MD, MSPH
Ellen Sigal, PhD
Harlan Weisman, MD

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
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Clyde Yancy, MD, MSc

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

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

These Methodology Committee Working Groups supported the development of PCORI’s draft methodology report and methodology standards and completed their work in 2012.

Committee as of Dec. 31, 2012.
Executive Compensation Committee
Steven Lipstein, MHA (Chair)
Kerry Barnett, JD
Lawrence Becker
Eugene Washington, MD, MSc

Nominating Committee
Robert Jesse, MD, PhD (Chair)
Gail Hunt
Freda Lewis-Hall, MD
Steven Lipstein, MHA
Robin Newhouse, PhD, RN
Eugene Washington, MD, MSc

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Desiree Frank, Executive Assistant
Anne Beal, MD, MPH, Deputy Executive Director, Chief Operating Officer
Denise Earlington, Executive Assistant
Mable Muldrow, Executive Assistant
Orlando Gonzales, MPA, Chief of Staff
Sean Grande, Project Associate

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Kara Odom-Walker, MD, MPH, MSHS, Program Officer
Katie Wilson, RD, MHSA, Senior Program Associate
Romana Hasnain-Wynia, MS, PhD, Program Director, Health Disparities Research
Ayodola Anise, MHS, Senior Program Associate
David Hickam, MD, MPH, Program Director, Comparative Effectiveness Research
Sarita Wahba, MS, Program Associate
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Rachael Fleurence, PhD, Acting Program Director, PCOR Methods
Kelly Dunham, MPP, Senior Program Associate
Natalie Wegener, Program Coordinator

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Aingea Kellom, MPA, Project Associate
Kim Holloway, Senior Administrative Assistant
Susan Hildebrandt, MA, Director, Stakeholder Engagement
Greg Martin, Deputy Director, Stakeholder Engagement
Lorraine Bell, RN, JD, MPH, Senior Program Associate
Celeste Brown, MPH, Program Associate

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William Silberg, Director, Communications
Marla Bolotsky, Associate Director, Digital Media
Annie Hammel, Senior Social Media Specialist
Tommesha Allen, Senior Administrative Assistant

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Martin Duenas, MPA, Director
James Hulbert, Contracts Administrator
Cammi Blackman, Project Coordinator
Kristen Metzger, MPA, MSCJ, Project Coordinator
Soknorntha Prum, MPH, Grants Coordinator

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Merenda Tate, MBA, MHRM, Assistant Controller, Treasury Operations
Silena Christopher, Administrative Assistant

Information Technology
James Convery, MBA, Director

Human Resources
Mitch Eisman, Director
Brittany Jones, Senior Administrative Assistant

Special Events and Planning
Mark Q. Freeman, Manager
Kelton Chapman, Assistant Manager
Jordan Elliker, Project Coordinator

Staff as of Dec. 31, 2012.
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III. Patient-Centered Outcomes Research Institute Financial Report, December 31, 2012 .... A12–A31

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Approved Research Awards and Contracts
Research Contracts Awarded January 2012–February 2013

PCORI’s RFP Evaluation Process

Technical and cost evaluation criteria are developed for each RFP solicitation and the weighted importance of each evaluation criterion is published in an RFP that is posted on our website. A notification is distributed via our email list and/or other vehicles as appropriate to the specific request. Submitted proposals are assessed in a careful process:

• The solicitation must comply with PCORI’s Conflict of Interest Policy; completion of a disclosure form is required.
• A PCORI Evaluation Team of procurement specialists and subject matter experts is convened and each technical proposal reviewed for merit by at least three reviewers who have been assessed for conflict of interest with the institution and personnel identified in all proposals under consideration.
• The cost proposals of the highest-scoring technical proposals are reviewed for reasonableness and accuracy.
• A Selection Committee of senior management identifies the potential contractor based on the “best value,” the combined technical and cost proposal scoring, and a verbal offer of award is made pending data collection, due diligence and acceptance.
• The verbal offer is followed by a Best and Final Offer negotiation and a contract is executed.
• Unsuccessful applicants are contacted and advised of their status. Unsuccessful applicants receive a formal debriefing upon request.

PCORI PILOT PROJECTS

<table>
<thead>
<tr>
<th>Project</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mind the Gap-Targeting Differences in Patients’ Current and Preferred Abilities</td>
<td>San Francisco State University</td>
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<td>Patient-Centered Care: What Factors Drive Outcomes in the Hospital Setting?</td>
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<td>Development of Methods for Identifying Child and Parent Health Outcomes</td>
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<td>Integrating Patient-Centered Outcomes in Arthritis Clinical Care</td>
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<td>Integrating and Comparing Community-Based Participatory and Conjoint Analysis</td>
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<td>A Modified Delphi Approach to Defining a Patient-Centered Community Health Center</td>
<td>University of California, Los Angeles</td>
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<td>Decision Support for Symptom and Quality of Life Management</td>
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<td>Effects of a Patient Driven Assessment Process with Complex Pain Patients (PDAP)</td>
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<td>Stakeholder Views of Streamlined Informed Consent Options for CER Studies</td>
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<td>Promoting Patient-Centered Counseling to Reduce Inappropriate Diagnostic Tests</td>
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<td>A Low-Cost Virtual Reality Gaming Platform for Neurorehabilitation of Hemiparesis</td>
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<td>Development of a Patient Centered Decision Tool for Nephrotic Syndrome Management</td>
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<td>Mobile Apps (MAPPS): Patient &amp; Caregiver Attitudes, Behaviors, and Knowledge</td>
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<td>Assessing and Reporting Heterogeneity of Treatment Effect in Clinical Trials</td>
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<td>Patient and Provider Perspectives on Reasons for Hospital Re-admissions</td>
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<td>Development and Pilot of Three Patient Decision Aids for Implanted Defibrillators</td>
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<td>Creation of the Person-Centered Wellness Home Across the Life Course</td>
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<td>Evaluating PROMIS Instruments and Methods for PCOR: Substance Use Treatment</td>
<td>University of Pittsburgh Medical Center</td>
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<td>Developing and Testing a Decision Support Tool for Primary Medication Adherence</td>
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<td>Influence &amp; Evidence: Understanding Consumer Choices in Preventive Care</td>
<td>University of Massachusetts Medical School</td>
<td>Barry Saver</td>
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<td>Measuring Patient Outcomes from High Tech Diagnostic Imaging Studies</td>
<td>HealthPartners Research Institute for Education and Research</td>
<td>Leif I. Solberg</td>
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<td>Group Model Building to Engage Patient &amp; Clinician Wisdom to Design Primary Care</td>
<td>Case Western Reserve University</td>
<td>Kurt Stange</td>
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<th>Contract Amount</th>
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<td>Methods to Increase Validity of Comparative Effectiveness Research in the Elderly</td>
<td>UNC Chapel Hill</td>
<td>Til Sturmer</td>
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<td>Addressing Mental Health Needs of Rural African Americans</td>
<td>University of Arkansas for Medical Sciences</td>
<td>Jan Greer Sullivan</td>
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<tr>
<td>Creating a Zone of Openness to Increase Patient-Centered Care</td>
<td>Palo Alto Medical Foundation Research Institute</td>
<td>Ming Tai-Seale</td>
<td>$674,264</td>
</tr>
<tr>
<td>Involving Nursing Home Residents and Families in Acute Care Transfer Decisions</td>
<td>Florida Atlantic University Board of Trustees</td>
<td>Ruth M. Tappen</td>
<td>$680,686</td>
</tr>
<tr>
<td>Health Team Support for Patient Informed Decision Making</td>
<td>University of California, San Francisco</td>
<td>David Thom</td>
<td>$671,478</td>
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<tr>
<td>An Approach to Capture Divergent Stakeholder Views on Future Research Needs</td>
<td>University of North Carolina Chapel Hill, Cecil G. Sheps Center for Health Services Research</td>
<td>Kathleen Thomas</td>
<td>$692,735</td>
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<tr>
<td>Medication-Taking Preferences &amp; Practices of Patients with Chronic Conditions</td>
<td>Washington State University</td>
<td>Roxanne Vandermause</td>
<td>$221,844</td>
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<tr>
<td>Patient-Centered Non-Routine Events to Identify Risks to Best Patient Outcomes</td>
<td>Vanderbilt University</td>
<td>Matthew B. Weinger</td>
<td>$698,398</td>
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<tr>
<td>Boot Camp Translation for Patient Centered Outcomes</td>
<td>University of Colorado—Denver</td>
<td>John M. Westfall</td>
<td>$686,314</td>
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<tr>
<td>A Community Partnership Approach for Advancing Burden Measurement in Rare Genetic Conditions</td>
<td>Medical University of South Carolina</td>
<td>Pamela Williams</td>
<td>$380,286</td>
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<tr>
<td>Methods for Analysis of Decision-Related Communication in Outpatient Care</td>
<td>Brown University</td>
<td>Ira Wilson</td>
<td>$642,462</td>
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<tr>
<td>Methodologies to Adjust for Respondent Status Effects on Health Outcomes</td>
<td>University of Iowa</td>
<td>Frederic Wolinsky</td>
<td>$637,901</td>
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<tr>
<td>Understanding Patient Preferences for Informed Decision-Making</td>
<td>Virginia Commonwealth University</td>
<td>Steven H. Woolf</td>
<td>$649,007</td>
</tr>
<tr>
<td>Comparing Dynamic Treatment Strategies in Patient-Centered Outcomes Research</td>
<td>Medical Technology &amp; Practice Patterns Institute, Inc.</td>
<td>Yi Zhang</td>
<td>$593,472</td>
</tr>
</tbody>
</table>

### PFA CYCLE 1 CONTRACTS

<table>
<thead>
<tr>
<th>Project</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Application Amount</th>
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</thead>
<tbody>
<tr>
<td>Cultural tailoring of educational materials to minimize disparities in HPV vaccination</td>
<td>University of Colorado Denver</td>
<td>Amanda Dempsey</td>
<td>$1,548,804.00</td>
</tr>
<tr>
<td>Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial</td>
<td>University of Alabama in Tuscaloosa</td>
<td>Beverly Thorn</td>
<td>$1,279,452.00</td>
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<tr>
<td>Improving Psychological Distress Among Critical Illness Survivors and Their Informal Caregivers</td>
<td>Duke University</td>
<td>Christopher Cox</td>
<td>$1,850,898.00</td>
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<tr>
<td>Presenting Patient-Reported Outcomes Data to Improve Patient and Clinician Understanding and Use</td>
<td>Johns Hopkins University</td>
<td>Claire Snyder</td>
<td>$697,104.34</td>
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<tr>
<td>Creating a Clinic-Community Liaison Role in Primary Care: Engaging Patients and Community in Health Care Innovation</td>
<td>Group Health Cooperative</td>
<td>Clarissa Hsu</td>
<td>$1,564,384.00</td>
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</tbody>
</table>
## Approved Research Awards and Contracts

<table>
<thead>
<tr>
<th>Project</th>
<th>Organization</th>
<th>Principal Investigator</th>
<th>Application Amount</th>
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<tbody>
<tr>
<td>Evaluation of a Patient-Centered Risk Stratification Method</td>
<td>Group Health Cooperative</td>
<td>Dan Cherkin</td>
<td>$1,892,297.00</td>
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<tr>
<td>for Improving Primary Care for Back Pain</td>
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<tr>
<td>Cognitive AED Outcomes in Pediatric Localization Related Epilepsy (COPE)</td>
<td>Emory University</td>
<td>David Loring</td>
<td>$2,071,577.40</td>
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<tr>
<td>Decision Support for Parents Receiving Genetic Information about</td>
<td>University of Michigan at Ann Arbor</td>
<td>David Sandberg</td>
<td>$1,373,164.00</td>
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<td>Child’s Rare Disease</td>
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<tr>
<td>Reducing Health Disparities in Appalachians with Multiple Cardiovascular</td>
<td>University of Kentucky</td>
<td>Debra Moser</td>
<td>$2,092,473.60</td>
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<td>Disease Risk Factors</td>
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<td>Shared Decision Making in the Emergency Department: The Chest Pain</td>
<td>Mayo Clinic</td>
<td>Erik Hess</td>
<td>$2,039,974.00</td>
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<td>Choice Trial</td>
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<tr>
<td>Selection of Peritoneal Dialysis or Hemodialysis for Kidney Failure</td>
<td>Arbor Research Collaborative for Health</td>
<td>Francesca Tentori</td>
<td>$1,898,390.00</td>
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<tr>
<td>Gaining Meaningful Information for Patients and Caregivers</td>
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<td>The Family VOICE Study (Value Of Information, Community Support, and</td>
<td>University of Maryland Baltimore</td>
<td>Gloria Reeves</td>
<td>$1,425,088.00</td>
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<td>Experience): a randomized trial of family navigator services versus</td>
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<td>usual care for young children treated with antipsychotic medication</td>
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<td>Improving Palliative and End-of-Life Care in Nursing Homes</td>
<td>University of Rochester</td>
<td>Helena Temkin-Greener</td>
<td>$1,468,738.00</td>
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<td>Optimizing Behavioral Health Homes by Focusing on Outcomes that Matter</td>
<td>UPMC Centerfor High-Value Health Care</td>
<td>James Schuster</td>
<td>$1,727,859.00</td>
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<td>Most for Adults with Serious Mental Illness</td>
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<td>Comparative effectiveness of rehabilitation services for survivors of</td>
<td>Duke University</td>
<td>Janet Prvu Bettger</td>
<td>$894,620.00</td>
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<td>an acute ischemic stroke</td>
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<td>Relative patient benefits of a hospital-PCMH collaboration within an</td>
<td>Brigham and Women’s Hospital</td>
<td>Jeffrey Schnipper</td>
<td>$1,905,175.00</td>
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<td>ACO to improve care transitions</td>
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<td>Innovative Methods for Parents and Clinics to Create Tools (IMPACCT)</td>
<td>Ochin, Inc</td>
<td>Jennifer DeVoe</td>
<td>$1,830,297.00</td>
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<td>for Kids’ Care</td>
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<td>Relapsed childhood neuroblastoma as a model for parental end-of-life</td>
<td>Dana-Farber Cancer Institute</td>
<td>Jennifer Mack</td>
<td>$985,992.00</td>
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<td>decision-making</td>
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<td>Long-term outcomes of community engagement to address depression</td>
<td>University of California Los Angeles</td>
<td>Kenneth Wells</td>
<td>$2,064,163.00</td>
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<td>outcomes disparities</td>
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<td>Patient-Identified Personal Strengths (PPS) vs. Deficit-Focused Models</td>
<td>Case Western Reserve University</td>
<td>Kurt Stange</td>
<td>$1,751,758.60</td>
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<td>of Care</td>
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<td>Comparative effectiveness of adolescent lipid screening and treatment</td>
<td>Tufts Medical Center</td>
<td>Laurel Leslie</td>
<td>$993,485.00</td>
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<td>strategies</td>
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<td>A Comparison of Non-Surgical Treatment Methods for Patients with Lumbar</td>
<td>University of Pittsburgh at Pittsburgh</td>
<td>Michael Schneider</td>
<td>$1,707,751.00</td>
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<td>Spinal Stenosis</td>
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<td>Comparative Effectiveness of Intravenous v. Oral Antibiotic Therapy</td>
<td>Children’s Hospital of Philadelphia</td>
<td>Ron Keren</td>
<td>$1,933,655.00</td>
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<td>for Serious Bacterial Infections</td>
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<td>Extension Connection: Advancing Dementia Care for Rural and Hispanic</td>
<td>University of Iowa</td>
<td>Ryan Carnahan</td>
<td>$1,626,680.00</td>
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<td>Populations</td>
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<td>Shared Medical Decision Making in Pediatric Diabetes</td>
<td>Nemours Children’s Clinic</td>
<td>Tim Wysocki</td>
<td>$2,092,090.00</td>
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</tbody>
</table>
## CONTRACT RESEARCH (INCLUDING RFPs)

<table>
<thead>
<tr>
<th>Project</th>
<th>Organization</th>
<th>Contract Amount</th>
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</thead>
<tbody>
<tr>
<td>Pilot Project Monitoring for 50 PCORI Funding Announcements</td>
<td>AcademyHealth</td>
<td>$806,002</td>
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<tr>
<td>Analyzing results from researchers and non-researchers collected during public comment periods</td>
<td>American Institutes for Research</td>
<td>$184,330</td>
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<tr>
<td>Drafting of responses to comments provided by the public in response to PCORI’s draft methodology report</td>
<td>Berry Consultants</td>
<td>$74,200</td>
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<tr>
<td>Value-of-Information Analysis for Patient-Centered Outcomes Research Prioritization</td>
<td>Duke University</td>
<td>$84,728</td>
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<tr>
<td>Methods for Involving Patients in Topic Generation for Patient-Centered Comparative Effectiveness Research</td>
<td>Hayes</td>
<td>$30,100</td>
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<tr>
<td>Survey Research Services</td>
<td>InCrowd, Inc.</td>
<td>$245,900</td>
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<tr>
<td>Facilitation services for Patient Engagement Workshop</td>
<td>Institute for Alternative Futures</td>
<td>$117,955</td>
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<tr>
<td>Minimal Standards in the Prevention and Handling of Missing Data in Observational and Experimental Patient Centered Outcomes Research</td>
<td>Johns Hopkins University School of Medicine</td>
<td>$69,231</td>
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<tr>
<td>Eliciting Patient Perspective in Patient-Centered Outcomes Research: A Meta Narrative Systematic Review</td>
<td>Mayo Clinic, Knowledge and Evaluation Research Unit</td>
<td>$176,025</td>
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<tr>
<td>Peer Review: A Research Priority</td>
<td>Medical College of Wisconsin</td>
<td>$12,484</td>
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<tr>
<td>Analysis of Focus Group Discussions of Working Definitions of Patient-Centered Outcomes Research</td>
<td>NORC at the University of Chicago</td>
<td>$90,797</td>
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<tr>
<td>Analysis of Public Comments on Working Definition of Patient-Centered Outcomes Research</td>
<td>NORC at the University of Chicago</td>
<td>$34,906</td>
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<tr>
<td>Enhancing the Patient’s Voice: Standards in the Design and Selection of Patient-Reported Outcomes Measures (PROMs) for Use in Patient-Centered Outcomes Research</td>
<td>Northwestern University</td>
<td>$83,908</td>
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<tr>
<td>PCORI Expert Interviews Project; Involving Patients in Research Best Practices from the Expert Interviews Project</td>
<td>The Center for Evidence-Based Policy, Oregon Health &amp; Science University</td>
<td>$295,212</td>
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<tr>
<td>Standards in the Conduct of Registry Studies for Patient-Centered Outcomes Research; Review of Guidance for Registry Standards—Non-Technical Summary</td>
<td>Science Applications International Corporation</td>
<td>$87,066</td>
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<tr>
<td>Development of a Methodological Standards Report: Topic # 3: The Design and Selection of Patient-Reported Outcomes Measures (PROMs) for Use in Patient Centered Outcomes Research</td>
<td>Oxford Outcomes</td>
<td>$69,705</td>
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<tr>
<td>Science Review Officer (SRO) Support</td>
<td>Science Applications International Corporation</td>
<td>$2,270,596</td>
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<tr>
<td>Comprehensive Inventory of Research Networks</td>
<td>University of California at San Diego</td>
<td>$199,236</td>
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<td>Integrating patients voices in study design elements with a focus on hard-to-reach populations</td>
<td>Pharmaceutical Health Services Research Department, University of Maryland School of Pharmacy</td>
<td>$125,000</td>
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</table>
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 February 8, 2013

Financial Associations:
• University of North Carolina at Chapel Hill (Employer)
• NIH/NINR (ended 12/31/12)
• Robert Wood Johnson Foundation—Executive Nurse Fellows Program

Personal Associations:
• National Organization of Nurse Practitioner Faculties—President
• American Association of Nursing—Member
• National League for Nursing—Member
• American Association of Colleges of Nursing, Practice Leadership Network—Member
• American Nurses Association—Member
• North Carolina Nurses Association—Member
• American Heart Association—Member
• American Academy of Nursing—Member

Kerry Barnett, JD
As of February 24, 2013

Financial Associations:
• Cambia Health Solutions (Employer)
• The Regence Group and affiliates

Personal Associations:
• Rise Health—Board member
• United Way of the Columbia Willamette—Board member

Lawrence Becker
As of January 29, 2013

Financial Associations:
• Xerox Corporation (Employer)
• Stock ownership:
  - Aetna, Inc.
  - GE
  - Johnson & Johnson, Inc.
  - Merck
  - Pfizer, Inc.
  - SPDR Biotech
  - The Travelers Companies, Inc.
  - Ventas

• LSB Consultants, LLC—company owned by wife
• Benfield Group

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; no changes since this disclosure

Financial Associations:
• Director, Agency for Healthcare Research and Quality (Employer)

Personal Associations:
• Institute of Medicine—Member
• American College of Physicians—Member
• 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

Allen Douma, MD
As of June 10, 2013

Financial Associations:
None Identified

Personal Associations:
• AARP—Board member
• Jefferson Regional Health Alliance—Board member

Arnold Epstein, MD
As of February 13, 2013

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 employer

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 February 18, 2013

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
• Prezazor, Inc.

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
Leah Hole-Marshall, JD  
As of February 11, 2013

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

Personal Associations:  
None Identified

Gail Hunt  
As of February 19, 2013

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 March 5, 2013

Financial Associations:
- Department of Veterans Affairs—Principal Deputy Undersecretary 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 March 1, 2013

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
- Institute of Healthcare Improvement—Chair, Scientific Advisory Group
- Medtronic, Inc.—Principal Investigator on grant through Yale University
- Centrix Technologies Pvt. Ltd.—Education Lectures
- Premier, Inc.—Consultant
- Fujvai Hospital—Consultant

Personal Associations:
- American College of Cardiology—Board member
- CV Outcomes, Inc.—Secretary
- American Board of Internal Medicine—Board member
- Minnesota Medical Foundation
- Case Western Reserve Medical School, Board of Visitors
- Chari & Syringomyelia Foundation

Richard E. Kuntz, MD, MSc  
As of February 28, 2013

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
- Chari & Syringomyelia Foundation

Sharon Levine, MD  
As of January 25, 2013

Financial Associations:
- The Permanente Medical Group (Employer)
- American Medical Association—spouse’s employer

Personal Associations:
- California Association of Physician Groups (CAPG)—Board member, Executive Committee member
- California Medical Association/AMA, Member

Freda Lewis-Hall, MD  
As of February 6, 2013

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
- Institute of Medicine—Member
- Save the Children (STC)—Board Member
- NCATS Advisory Council—Council Member
- NCAT/Cures Acceleration Network Review (CAN)—Chairperson

Steven Lipstein, MHA (Vice Chair)  
As of February 4, 2013

Financial Associations:
- BJC HealthCare—President and CEO (Employer)

Personal Associations:
- Emory University Healthcare Innovation Program—Trustee
- Washington University—Trustee
- Missouri Hospital Association—Trustee
- Boston Children's Hospital—Relative is employee
- St. Louis Regional Health—Treasurer
Grayson Norquist, MD, MSPH  
As of January 28, 2013

Financial Associations:
• University of Mississippi Medical School—Chair, Department of Psychiatry (Employer)

Personal Associations:
• American Psychiatric Association (APA)—Fellow
• APA Council on Research and Quality—Member
• American Psychiatric Foundation (component of APA)—Board of Directors
• AcademyHealth—Fellow
• Mississippi Coast Interfaith Disaster Task Force
• Mississippi Psychiatric Association—Member of Executive Board
• Tougaloo College
• UCLA, Department of Psychiatry and Biobehavioral Sciences

Financial Associations:
As of February 1, 2013

Eugene Washington, MD, MSc (Chair)
As of February 1, 2013

Financial Associations:
• UCLA—Vice Chancellor and Dean (Employer)
• The California Wellness Foundation—Board member
• Johnson & Johnson—Director

Personal Associations:
None identified

Harlan Weisman, MD  
As of February 6, 2013

Financial Associations:
• Stock Ownership:
  - Johnson & Johnson
  - Coronado Biosciences

Personal Associations:
• Coronado Biosciences, Inc.—Chairman and CEO
• And-One Consulting—Managing Director
• ControlRad Systems—Director

Robert Zwolak, MD, PhD  
As of February 26, 2013

Financial Associations:
• Dartmouth-Hitchcock Clinic (Employer)
• US Department of Veterans Affairs (Employer)
• Society for Vascular Surgery—Consultant
• Honoraria for Visiting Professorships:
  Various academic medical centers
• Stock Ownership:
  - EVA Corporation, medical device manufacturer

Personal Associations:
• Intersocietal Commission for Accreditation of Carotid Stent Facilities, Board of Directors
• AMA/Specialty Society Relative Value Update Committee—Prior full member, current member of two work groups (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 work groups of lesser status than Governor
• Dartmouth Medical School—Professor (no salary)

Methodology Committee

Naomi Aronson, PhD  
As of January 28, 2013

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

Personal Associations:
• Pew Charitable Trust, Technical Advisor, Medical Device Registry Project
• GAPPNET Planning Committee
• Health Technology Assessment International Health Policy Forum
• Institute of Medicine Genomics Roundtable
• Steering Committee of the Chicago Area—DEcIDE 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

Ethan Basch, MD, MSc  
As of January 17, 2013

Financial Associations:
• University of North Carolina, Chapel Hill (Employer)
• Memorial Sloan-Kettering Cancer Center (Employer)

Personal Associations:
• National Cancer Institute—Board of Scientific Advisors
• International Society for Quality of Life Research—Board Member
• Alliance for Clinical Trials in Oncology—Chair
• American Society of Clinical Oncology—Task Force Chair

Alfred O. Berg, MD, MPH  
As of January 25, 2013

Financial Associations:
• University of Washington, Seattle, NIH Investigator (Employer)

Personal Associations:
• Member, Board on Population Health and Public Health Practice, Institute of Medicine
• Member, American Academy of Family Physicians
• Member, Society of Teachers of Family Medicine

David Flum, MD, MPH
As of March 5, 2013

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)
• American Academy of Orthopaedic Surgeons—Speaker (4/12–13/2012; 8/5–6/2012)
• Covidien—Speaker (4/28–5/5/2012)
• NH Grampian—Speaker (4/28–5/5/2012)
• Nestlé—Speaker (9/21–23/2012; 1/10–14/2013)
• American College of Surgeons—Surgical Research Committee Chair (ongoing) & Outcomes Research Course Chair (11/7–10/2012)
• Australia New Zealand Hepato—Biliary Association—Speaker (10/30–11/7/2012)

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. Hanks Surgical Society
• Seattle Surgical Society
• Surgical Outcomes Club

Sherine Gabriel, MD, MSc (Chair)
As of February 19, 2013

Financial Associations:
• Mayo Clinic (Employer)
• Hoffman-LaRoche
• National Institutes of Health

Personal Associations:
• FDA/CDER Drug Safety and Risk Management Advisory Committee—Member (2010–present)

• Chair, FDA/CDER Drug Safety and Risk Management Advisory Committee—Member (2011–present)
• External Advisory Board, University of Puerto Rico Post-doctoral Master of Science in Clinical Research Program, School of Medicine and School of Health Professions—Member (2006–present)
• Executive Board, Observational Medical Outcomes Partnership, Foundation for the NIH—Member (2008–present)
• Scientific Advisory Board, Excellence in Rheumatology—Member (2010–present)
• International Coordination Council, Bone and Joint Decade/Initiative—Member (2010–present)
• CTSA Academic-Industry Working Group—Chair (2010–present)
• Steering Committee, Actemra Cardiovascular Outcomes Trial (ENTRACTE), Roche—Member (2009–present)
• Pharmacoepidemiology Advisory Board, Genentech—Member (2009–present)
• External Research Education Advisory Board, University of Kentucky CTSA—Member (2011–present)
• External Research Education Advisory Committee, Georgetown University—Member (2011–present)
• Oversight Board, Welcome Trust, HRB Dublin Centre for Clinical Research—Member (2011–present)

Steven Goodman, MD, MHS, PhD
As of February 28, 2013

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:
• Editor, Clinical Trials: Journal of the Society for Clinical Trials
• Society for Clinical Trials—Member
• American Academy of Epidemiology—Member

Mark Helfand, MD, MS, MPH
As of February 8, 2013

Financial Associations:
• Employer: Portland VA Medical Center, Portland, OR (Hospital and Clinics)
• Employer: Oregon Health & Science University, Portland, OR (Hospital and Clinics)

• Research Grants, Contracts, Consulting, Teaching:
  • US Department of Veterans Affairs (grants)
  • Agency for Healthcare Research & Quality, US DHHS (contracts), Consumers Union (Consultant)
  • Lectures at several universities in the US and abroad
  • Daughter is an employee of the Univ. of California

Personal Associations:
• AcademyHealth
  • Member, serve on committees
• American College of Physicians—Member
• Society for General Internal Medicine—Member
• Society for Medical Decision Making—Member, serve on committees
• U.S. Cochrane Center (Advisory Board)

John Ioannidis, MD, DSc
As of February 11, 2013

Financial Associations:
• Professor, Stanford University School of Medicine (Employer)

Personal Associations:
• Editor-in-chief, European Journal of Clinical Investigation
• Editorial member of 30 international peer-reviewed journals

Michael S. Lauer, MD
As of February 27, 2013

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 February 28, 2013

Financial Associations:
• University of Chicago (Employer)
• Novartis
• CVS
• ABIM
• Peoplechart
• Cubist
• InHealth
• Centers for Medicare and Medicaid Innovation
• 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:
- ABIM, SGIM, SHM, MDM—Member
- University of Chicago

Brian S. Mittman, PhD
As of February 11, 2013

Financial Associations:
- US Department of Veterans Affairs, VA Greater Los Angeles Healthcare System (Employer; wife’s employer)
- Sepulveda Research Corporation (VA Nonprofit Research Foundation, Employer)
- Kaiser Permanente Southern California, Department of Research and Evaluation (Employer) UCLA School of Medicine (Employer)
- Harvard University Dana Farber Cancer Institute (Consultant, NIH grant)
- Lewin Group (Speaking honorarium, AHRQ Chartered Value Exchange program)
- National Institutes of Health (Consultant, NIH/VA training program)
- Purdue Pharmaceuticals (Consultant, FDA Risk Evaluation & Mitigation Strategy CME program), RAND Corporation (Consultant)
- Sanofi; Precision Health Economics (Consultant, Comparative Effectiveness Working Group)
- Stanford University (Speaking honorarium, RWJF training program), University of Iowa (Consultant, NIH and RWJF grants)
- University of Washington in St. Louis (Consultant, NIH training grant)
- Westat (Consultant, AHRQ Health Care Innovations Exchange)

Personal Associations:
- Association of American Medical Colleges (Member, Advisory Panel on Research)
- AcademyHealth (Member, Methods Council; Member, advisory group, Delivery System Science Fellowship program)
- Knowledge Translation Canada (Member, International Scientific Advisory Board)
- Singapore Ministry of Health (Member, International Scientific Advisory Board for Health Services Research)

Robin Newhouse, PhD, RN
As of January 31, 2013

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

Personal Associations:
- Research and Scholarship Advisory Council, Sigma Theta Tau International Honor Society of Nursing—Chair
- American Nurses Credentialing Center—Research Council Member
- Review Committee for Student Posters, 2012 AcademyHealth Research Meeting—Chair
- AcademyHealth, member, Alice S. Hersh New Investigator Award Selection Committee and 2013 Annual Research Meeting Planning Committee
- Sigma Theta Tau International Honor Society of Nursing—Chair of Research & Scholarship
- American Nurses Credential Center—Research Council Member

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
- Harvard School of Public Health
- WHISCON LLC
- Refron, Inc.
- Booz & Co.

Personal Associations:
- Member of:
  - ISPE
  - ISPOR
  - ASCPT
  - ACE
  - Fellow of:
    - The American College of Clinical Pharmacology
    - The American College of Epidemiology
    - International Society of Pharmacoepidemiology

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 February 7, 2013

Financial Associations:
- Yale University (Employer)
- National Institutes of Health Hartford Foundation
- Journal of the American Medical Association (JAMA)—Viewpoint editor
- MacArthur Foundation
- Johns Hopkins University—Lecturer
- Tufts University—Invited speaker

Personal Associations:
- None Identified

Clyde Yancy, MD, MSc
As of June 18, 2013

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)
• American Hospital Association—Committee Member
• American College of Cardiology—Committee 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—Member

PCORI Executive Staff

Joe V. Selby, MD, MPH
As of September 14, 2011; no changes since this disclosure

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

Anne Beal, MD, MPH
As of March 20, 2013

Financial Associations:
• PCORI—Deputy Executive Director and Chief Operating Officer (salaried position)
• Aetna (investments)

Personal Associations:
None Identified
Patient-Centered Outcomes Research Institute

Financial Report
December 31, 2012
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Independent Auditor's Report

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

Report on the Financial Statements
We have audited the accompanying financial statements of Patient-Centered Outcomes Research Institute (PCORI) which comprise the statements of financial position as of December 31, 2012 and 2011, and the related statements of activities, cash flows and functional expenses for the years then ended and the related notes to the financial statements.

Management's Responsibility for the Financial Statements
Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility
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 from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor’s judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity’s preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.
Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of PCORI as of December 31, 2012 and 2011, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Other Matters

Management’s Discussion and Analysis, on pages 3 – 8, is presented to supplement the basic financial statements and is not a part of the basic financial statements. We have applied certain limited procedures to the supplementary information in accordance with auditing standards generally accepted in the United States of America, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management’s responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audit of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

Other Reporting Required by Government Auditing Standards

In accordance with Government Auditing Standards, we have also issued our report dated March 12, 2013 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 internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with Government Auditing Standards in considering PCORI’s internal control over financial reporting and compliance.

McGladrey LLP

Vienna, Virginia
March 12, 2013
Patient-Centered Outcomes Research Institute

Management's Discussion And Analysis

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by federal law (42 U.S.C. 1301 et seq.) in 2010 to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis." PCORI also is charged with disseminating the results of that research, focusing on "health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items" studied.

PCORI is a 501(c)(3) non-profit corporation, governed by a 21-member multi-stakeholder Board of Governors, including 19 members appointed by the Comptroller General of the United States and the Directors of the Agency for Healthcare Research and Quality (AHRQ) and National Institutes of Health (NIH). By law, the Comptroller General 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 addition to its Board, PCORI's work is guided by a 17-member Methodology Committee charged with developing and advancing the science and methodologies of comparative clinical effectiveness research. Members of the Methodology Committee, also appointed by the Comptroller General, 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 is guided by three committees with particular areas of focus – Communications, Outreach and Engagement; Finance, Audit and Administration; and Program Development – and special committees on Scientific Publications and Conflicts of Interest. To assist in its work, the Methodology Committee established working groups on Patient-Centeredness, Research Prioritization, Research Methods, and Report Assimilation. These were dissolved following the delivery of the Methodology Committee's draft Report and Standards to PCORI's Board, as required by law, in May 2012.

Current Activities

Organizational Structure and Focus

PCORI focused in 2012 on solidifying and enhancing the infrastructure, policies, and procedures needed for the effective functioning of a new research institute; carrying out foundational and organizational tasks mandated by PCORI's establishing legislation; starting to build a broad-based portfolio of patient-centered comparative effectiveness research; and continuing to develop the community of engaged stakeholders essential to the conduct, refinement, and eventual dissemination of the results of that work. The institute had a staff of 47 as of the end of the year, including full-time or acting directors for four of its five scientific program areas and directors of patient and stakeholder engagement, engagement research, communications, contract management, finance, human resources and information technology.

Engagement as a Path to Rigorous Research

PCORI’s focus on engagement has been a core commitment and guiding principle virtually since the institute’s creation and is memorialized in the mission statement adopted by the Board 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."
Patient-Centered Outcomes Research Institute

Management’s Discussion And Analysis

In 2012, PCORI used live convening and a range of online tools to gain a broad array of stakeholder input to guide its work, attracting thousands of patients, caregivers, researchers, clinicians, advocacy groups, and other stakeholders. Open bimonthly Board meetings featured public comment periods and were webcast. Methodology Committee members met with patients, caregivers, and dozens of clinical research, and patient advocacy organizations in the course of its work. More than a dozen workshops, roundtables, and other gatherings facilitated PCORI’s ongoing dialogue with stakeholders as it pursued its work, including as it developed and refined its National Priorities for Research and Research Agenda and Methodology Standards, promoted development of a patient-centered research community, and advanced its process for identifying research specific topics for study through online solicitation of research questions.

Among the most visible examples of this commitment to engagement in research were the requirements outlined in PCORI’s funding announcements, including that applicants involve patients and other stakeholders as meaningful partners in their research projects. As part of its effort to support this focus, a PCORI Challenge initiative was launched late in the year, using a “crowdsourcing” model to seek proposals for creating a “matching service” designed to connect researchers and patients as prospective research partners.

Supporting outreach and communications about these events, PCORI substantially grew its online and social media presence throughout the year. PCORI’s web site recorded a total of 376,881 visits by 178,631 unique visitors and nearly 1.5 million page views. At year’s end, PCORI nearly quadrupled the size of its e-mail list to about 7,600 and saw its Twitter following increase nearly ten-fold. These audiences received regular updates from PCORI about events, funding opportunities and chances to provide meaningful input. In addition to assisting the Science team in its topic generation and research prioritization work as noted above, PCORI’s web site also served as a tool to solicit applicants for the growing pool of scientific and stakeholder reviewers needed to assess funding proposals.

Definition of Patient-Centered Outcomes Research (PCOR) Adopted

In March, the Board adopted a revised draft of a document defining “patient-centered outcomes research (PCOR),” something not widely agreed to within professional circles at the time PCORI was established. Such a definition was one of PCORI’s foundational tasks, designed to help clarify its focus and scope of work. A draft definition was developed 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.

Pilot Projects Program Issues 50 Awards

In April, the Board approved a slate of 50 PCORI Pilot Projects awards, funding $31 million in research, in 24 states and the District of Columbia, over two years. PCORI developed the program to support projects in eight areas of interest that would 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 prepared the recommended slate of projects for Board consideration.

National Priorities for Research and Research Agenda Adopted

In May, the Board adopted the institute’s legally mandated research roadmap, its National Priorities for Research, and Research Agenda. A draft version, development of which began in August 2011, had been released for a 53-day public comment in January, 2012. It was revised based on an analysis of the approximately 450 comments received during the comment period through a broad range of outreach and promotional efforts, including a national dialogue that attracted some 800 people to both the live event in Washington, D.C., and a simultaneous webcast, numerous small-group meetings with stakeholders, extensive online outreach, and digital advertising.
Patient-Centered Outcomes Research Institute

Management's Discussion And Analysis

The priorities and agenda, which are the basis for PCORI's calls for research funding, include the following areas: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; Addressing Disparities; and Accelerating Patient-Centered Outcomes Research and Methodological Research. They were written to be intentionally broad and do not name specific conditions or treatments that PCORI will examine. This approach recognized 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. However, even as the Priorities and Agenda were being finalized, PCORI was mapping out a process for moving toward identifying specific topics for funding, following a complementary two-path process that included both researcher-initiated proposals and patient/stakeholder-initiated proposals. As part of this effort, PCORI initiated a process for developing a set of multi-stakeholder Advisory Panels to assist in developing future funding announcements.

Developing PCORI's First Methodology Report
The Methodology Committee completed work on its draft report and standards for patient-centered comparative effectiveness research, which, along with a translation table and set of research recommendations, are required tools for guiding the Board in overseeing PCORI's research agenda. Four working groups on Patient-Centeredness, Research Priorities, Research Methods, and Report Assimilation were established to assist the Committee which also relied on input from leading methodologists from around the country and a set of expert background reports to produce the draft report and standards. These were delivered to the Board, as required by law, in May 2012, and opened to public comment for 54 days. After receiving more than 1,200 comments from 124 individuals and organizations, the standards were revised and adopted by the Board at its September meeting in Boston; the Committee also presented the Board with a set of research recommendations. A revised version of the draft report will be delivered to the Board in the spring of 2013.

Primary Research Funding Launched and Initial Awards Approved
PCORI launched its first round of primary research funding calls in May, issuing PCORI Funding Announcements (PFAs) associated with the first four of its National Priorities for Research. A PFA based on the fifth priority was issued in November, with applications due Jan. 15, 2013; additional PFAs under this priority are expected to be released later in 2013.

PCORI received 483 applications under the first cycle of this initial round of funding; proposals for "Assessment of Prevention, Diagnosis and Treatment Options" were most common, accounting for 44% of all applications received (40% of PFA funding is dedicated to this priority area). After a two-stage review involving some 105 scientists, patients and other stakeholders, PCORI's Board, on December 18, approved a slate of 25 projects in 17 states totaling nearly $40.7 million in funding over three years. A second funding cycle under the first four National Priorities for Research opened in September; 434 applications were received by the mid-December deadline.

Recognizing the need to speed the release of funding announcements to support patient-centered studies on specific research issues, PCORI moved in 2012 to augment its ongoing broad PFA process with a process of selecting specific high-impact research topics for potential funding calls. PCORI's Board approved three such topics from a potential slate of 11 -- uterine fibroids, fall prevention in the elderly and treatment of severe asthma in African-Americans and Hispanics/Latinos. PCORI staff will identify two additional topics in early 2013 to be considered for additional targeted announcements. Multi-stakeholder working groups will then help staff consider whether to proceed with funding announcements, which would be targeted for release in the spring of 2013.
Patient-Centered Outcomes Research Institute

Management's Discussion And Analysis

Additional Research Supported in 2012
In addition to funding through its Pilot Projects Program and PFAs, PCORI awarded a series of research contracts through a competitive RFP process. Those contracts included:

- Pilot Projects Monitoring Services.
- Results Analysis Services.
- Survey Research Services.

PCORI issued other RFPs during the year for operational services, including:

- Travel Management Services.
- Executive Search Services.
- Conference and Event Management Support Services.

Technical and cost evaluation criteria are developed for each RFP solicitation and the weighted importance of the evaluation criterion is published in a Request for Proposal (RFP) that is posted on PCORI's website in the Funding Announcements section (http://www.pcori.org/funding-opportunities/) and in the About Us/Operations and Finance section (http://www.pcori.org/about/operations-and-finance). A notification is distributed via the PCORI mailing list and/or other vehicles as appropriate to the specific request. Submitted proposals are assessed in a careful process that includes:

- The solicitation requires compliance with the PCORI Conflict of Interest Policy and the completion of a disclosure form.
- A PCORI Evaluation Team of procurement specialists and subject matter experts is convened and each technical proposal is reviewed for merit by at least three reviewers who have been assessed for conflict of interest with the institution and personnel identified in all proposals under consideration.
- The cost proposals for the highest scoring technical proposals are reviewed for reasonableness and accuracy.
- A Selection Committee of senior management identifies the potential contractor based on "best value," the combined technical and cost proposal scoring, and a verbal offer of award is made pending data collection, due diligence, and acceptance.
- The verbal offer is followed by a Best and Final Offer negotiation and a contract is executed.
- Unsuccessful applicants will be communicated with advising them of their status. If requested, unsuccessful applicants will be given a formal debriefing.

Financial Highlights
$1.26 billion was appropriated for Patient-Centered Outcome 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 statement in accordance with U.S. Generally Accepted Accounting Principles (GAAP), as issued by the Financial Accounting Standards Board (FASB). 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.
Patient-Centered Outcomes Research Institute

Management’s Discussion And Analysis

The following table highlights key components of PCORI’s financial statements during FY 2012:

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<th>Financial Data</th>
<th>FY 2012</th>
<th>FY 2011</th>
<th>Increase/ (Decrease)</th>
<th>Percentage Difference</th>
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<tr>
<td>Statement of Financial Position</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Assets</td>
<td>$ 302,753,342</td>
<td>$ 163,484,540</td>
<td>$ 139,268,802</td>
<td>85%</td>
</tr>
<tr>
<td>Liabilities</td>
<td>3,385,156</td>
<td>2,513,990</td>
<td>871,166</td>
<td>35%</td>
</tr>
<tr>
<td>Net Assets</td>
<td>$ 299,368,186</td>
<td>$ 160,970,550</td>
<td>$ 138,397,636</td>
<td>86%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement of Activities</th>
<th>FY 2012</th>
<th>FY 2011</th>
<th>Increase/ (Decrease)</th>
<th>Percentage Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$ 161,644,461</td>
<td>$ 120,024,106</td>
<td>$ 41,620,355</td>
<td>35%</td>
</tr>
<tr>
<td>Expenses</td>
<td>23,246,825</td>
<td>8,611,907</td>
<td>14,634,918</td>
<td>170%</td>
</tr>
<tr>
<td>Change in Net Assets</td>
<td>$ 138,397,636</td>
<td>$ 111,412,199</td>
<td>$ 26,985,437</td>
<td>24%</td>
</tr>
</tbody>
</table>

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 of 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:** As disclosed in the accompanying Statements of Financial Position and summarized in the table above, PCORI’s net assets increased $138,397,636 as a result of PCORI’s funding from US Government appropriations and transfers from the Federal Hospital Insurance (FHI) and the Federal Supplementary Medical Insurance (FSMI) Trust Funds less expenses of program and administrative supporting services. Specifically, PCORI’s total assets of $302,753,342 include $281,615,236 of funds held in Trust and $17,373,135 in cash. Total liabilities of $3,385,156 represent outstanding obligations and deferred rent and tenant improvement allowance.

**Statements of Activities:** In FY 2012, revenue and support totaled $161,644,461 of which $120,000,000 came from appropriations, $41,596,000 from the Federal Hospital Insurance and Federal Supplementary Medical Insurance trust funds and $48,461 from interest. The program activities of $15,172,537 are comprised of the program services of the Methodology Committee and the Communications, Engagement, and the Research Management departments. Expenses for support activities were $8,074,288. The combination of the revenue minus expenses yielded an excess of revenue over expenses totaling $138,397,636.

**Statements of Functional Expenses:** The $14,130,143 increase in program services between FY 2012 and FY2011 is primarily due to increased spending related to the preparation and release of the Methodology Report and the cost of expanded department activity in support of communication, engagement, and extramural research. In addition, the increase of $504,775 in administrative and other support services includes costs associated with building out infrastructure, permanent staffing, and the development of contracting capacity.
Patient-Centered Outcomes Research Institute

Management's Discussion And Analysis

Future Events

The long-term goals for PCORI have been defined as:

- Engaging patients and stakeholders so that they can participate in the PCORI research enterprise in a meaningful way;
- Advancing rigorous PCOR methods as the methodology standards become adopted as best practices across the country;
- Funding PCOR so that PCORI impacts decision-making, practice, and patient-outcomes;
- Communicating and disseminating PCOR findings;
- Developing a sustainable infrastructure for conducting PCOR.

The activities that are required to accomplish these goals are funded at the department level in calendar year 2013 and beyond and they include a shift towards permanent staffing, a significant investment in infrastructure, and the development of capacity for growth, internal controls, and compliance.

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 attention of the Finance Department, Patient-Centered Outcomes Research Institute, 1828 L Street, NW, Suite 900, Washington, DC, 20036. Additional information regarding PCORI's operations can be found at www.pcori.org.
Patient-Centered Outcomes Research Institute

Statements Of Financial Position
December 31, 2012 And 2011

<table>
<thead>
<tr>
<th>Assets</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>$ 17,373,135</td>
<td>$ 4,483,112</td>
</tr>
<tr>
<td>Amounts Held By PCOR Trust Fund (Note 2)</td>
<td>281,615,236</td>
<td>158,078,971</td>
</tr>
<tr>
<td>Prepaid Expenses</td>
<td>587,108</td>
<td>54,835</td>
</tr>
<tr>
<td>Deposits And Other Assets</td>
<td>521,698</td>
<td>708,469</td>
</tr>
<tr>
<td>Property And Equipment, net (Note 3)</td>
<td>2,656,165</td>
<td>159,153</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td><strong>$ 302,753,342</strong></td>
<td><strong>$ 163,484,540</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Liabilities And Net Assets</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>$ 2,382,607</td>
<td>$ 2,513,990</td>
</tr>
<tr>
<td>Deferred rent and tenant improvement allowance</td>
<td>1,002,549</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td><strong>3,385,156</strong></td>
<td><strong>2,513,990</strong></td>
</tr>
</tbody>
</table>

Commitments And Contingencies (Notes 4 And 5)

Net Assets

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrestricted</td>
<td>299,368,186</td>
<td>160,970,550</td>
</tr>
<tr>
<td><strong>Total net assets</strong></td>
<td><strong>$ 302,753,342</strong></td>
<td><strong>$ 163,484,540</strong></td>
</tr>
</tbody>
</table>

See Notes To Financial Statements.
Patient-Centered Outcomes Research Institute

Statements Of Activities
Years Ended December 31, 2012 And 2011

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue and support:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal appropriations (Note 2)</td>
<td>$120,000,000</td>
<td>$120,000,000</td>
</tr>
<tr>
<td>Transfers from the Federal Hospital Insurance (FHI) and the Federal Supplementary Medical Insurance (FSMI) trust funds (Note 2)</td>
<td>41,596,000</td>
<td>-</td>
</tr>
<tr>
<td>Interest income</td>
<td>48,461</td>
<td>24,106</td>
</tr>
<tr>
<td><strong>Total revenue and support</strong></td>
<td><strong>161,644,461</strong></td>
<td><strong>120,024,106</strong></td>
</tr>
</tbody>
</table>

Expenses:
Program services:
  Research                         | 8,115,435 | 1,180,910 |
  Communications, outreach, and engagement | 6,060,954 | 1,848,077 |
  Methodology                       | 4,392,868 | 1,410,127 |
  **Total expenses**                | **18,569,257** | **4,439,114** |

Supporting services:
  Administrative – general         | 3,095,366 | 3,166,048 |
  Administrative – board           | 1,582,202 | 1,006,745 |
  **Total expenses**               | **4,677,568** | **4,172,793** |

**Change in net assets**         | **138,397,636** | **111,412,199** |

Net assets:
  Beginning                        | **160,970,550** | **49,558,351** |

  Ending                          | **$299,368,186** | **$160,970,550** |

See Notes To Financial Statements.
Patient-Centered Outcomes Research Institute

Statements Of Cash Flows
Years Ended December 31, 2012 And 2011

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash Flows From Operating Activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in net assets</td>
<td>$138,397,636</td>
<td>$111,412,199</td>
</tr>
<tr>
<td>Adjustments to reconcile change in net assets to net cash provided by operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>348,109</td>
<td>-</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>167,322</td>
<td>-</td>
</tr>
<tr>
<td>Changes in assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Increase) decrease in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amounts held by PCOR Trust Fund</td>
<td>(123,536,265)</td>
<td>(108,440,106)</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>(532,273)</td>
<td>(54,835)</td>
</tr>
<tr>
<td>Deposits and other assets</td>
<td>186,771</td>
<td>(708,469)</td>
</tr>
<tr>
<td>Increase (decrease) in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>(131,383)</td>
<td>2,187,620</td>
</tr>
<tr>
<td><strong>Net cash provided by operating activities</strong></td>
<td>14,899,917</td>
<td>4,396,409</td>
</tr>
</tbody>
</table>

Cash Flow From Investing Activities

| Purchases of property and equipment | (2,845,121) | (148,122) |
| Reimbursement of leasehold improvements by landlord | 835,227 | - |
| **Net cash used in investing activities** | (2,009,894) | (148,122) |

**Net increase in cash**

| 12,890,023 | 4,248,287 |

Cash:

| Beginning | 4,483,112 | 234,825 |
| Ending    | $17,373,135 | $4,483,112 |

Supplemental Schedule Of Noncash Investing Activities

| Property and equipment included in accounts payable and accrued expenses | $10,180 | $11,031 |

See Notes To Financial Statements.
# Statement Of Functional Expenses
## Year Ended December 31, 2012

<table>
<thead>
<tr>
<th>Program Services</th>
<th>Supporting Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Research</td>
</tr>
<tr>
<td>Directors’ compensation</td>
<td>$ -</td>
</tr>
<tr>
<td>Salaries and wages – other</td>
<td>810,153</td>
</tr>
<tr>
<td>Other professional services</td>
<td>4,721,873</td>
</tr>
<tr>
<td>Contracts</td>
<td>-</td>
</tr>
<tr>
<td>Employee benefits/payroll taxes</td>
<td>322,272</td>
</tr>
<tr>
<td>Contracting capacity resources</td>
<td>978,564</td>
</tr>
<tr>
<td>Conferences, conventions, meetings</td>
<td>55,281</td>
</tr>
<tr>
<td>Rent, parking, other occupancy</td>
<td>229,110</td>
</tr>
<tr>
<td>Travel</td>
<td>274,220</td>
</tr>
<tr>
<td>Temporary help</td>
<td>103,916</td>
</tr>
<tr>
<td>Information technology</td>
<td>157,864</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>72,745</td>
</tr>
<tr>
<td>Legal fees</td>
<td>10,424</td>
</tr>
<tr>
<td>Accounting fees</td>
<td>-</td>
</tr>
<tr>
<td>Research</td>
<td>187,468</td>
</tr>
<tr>
<td>Telephone and communications</td>
<td>30,699</td>
</tr>
<tr>
<td>Supplies</td>
<td>35,296</td>
</tr>
<tr>
<td>Reviewer services</td>
<td>84,700</td>
</tr>
<tr>
<td>Printing and copying</td>
<td>6,275</td>
</tr>
<tr>
<td>Management fees</td>
<td>26,047</td>
</tr>
<tr>
<td>Advertising</td>
<td>-</td>
</tr>
<tr>
<td>Postage and shipping</td>
<td>2,031</td>
</tr>
<tr>
<td>Insurance – non-employee related</td>
<td>-</td>
</tr>
<tr>
<td>Books, subscriptions, references</td>
<td>4,577</td>
</tr>
<tr>
<td>Equipment rental and maintenance</td>
<td>1,920</td>
</tr>
<tr>
<td>Bank/payroll fees</td>
<td>-</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-</td>
</tr>
</tbody>
</table>

$ 8,115,435 $ 6,060,964 $ 4,392,868 $ 18,569,267 $ 3,095,366 $ 1,592,202 $ 4,677,868 $ 23,246,825

See Notes To Financial Statements.
Patient-Centered Outcomes Research Institute

Statement Of Functional Expenses
Year Ended December 31, 2011

<table>
<thead>
<tr>
<th></th>
<th>Program Services</th>
<th>Supporting Services</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Communications,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outreach, And</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Engagement</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methodology</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Program</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Directors’ compensation</td>
<td>$ -</td>
<td>$ 291,432</td>
<td>$ 291,432</td>
</tr>
<tr>
<td>Salaries and wages – other</td>
<td>65,239</td>
<td>61,870</td>
<td>209,630</td>
</tr>
<tr>
<td>Other professional services</td>
<td>359,824</td>
<td>1,067,103</td>
<td>665,380</td>
</tr>
<tr>
<td>Management fees</td>
<td>682,794</td>
<td>479,979</td>
<td>130,967</td>
</tr>
<tr>
<td>Contracting capacity resources</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Conferences, conventions, meetings</td>
<td>3,736</td>
<td>160,840</td>
<td>164,376</td>
</tr>
<tr>
<td>Travel</td>
<td>10,553</td>
<td>67,883</td>
<td>90,369</td>
</tr>
<tr>
<td>Legal fees</td>
<td>47,715</td>
<td>-</td>
<td>95,430</td>
</tr>
<tr>
<td>Employee benefits/payroll taxes</td>
<td>9,763</td>
<td>14,693</td>
<td>36,806</td>
</tr>
<tr>
<td>Rent, parking, other occupancy</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Advertising</td>
<td>-</td>
<td>77,960</td>
<td>-</td>
</tr>
<tr>
<td>Focus groups</td>
<td>-</td>
<td>62,649</td>
<td>-</td>
</tr>
<tr>
<td>Accounting fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Information technology</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Insurance – non-employee related</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Interim researchers</td>
<td>-</td>
<td>15,475</td>
<td>-</td>
</tr>
<tr>
<td>Equipment rental and maintenance</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Telephone and telecommunications</td>
<td>1,199</td>
<td>1,587</td>
<td>4,506</td>
</tr>
<tr>
<td>Supplies</td>
<td>-</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>Books, subscriptions, references</td>
<td>87</td>
<td>3,850</td>
<td>67</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Printing and copying</td>
<td>-</td>
<td>314</td>
<td>314</td>
</tr>
<tr>
<td>Bank/payroll fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Postage and shipping</td>
<td>-</td>
<td>77</td>
<td>77</td>
</tr>
</tbody>
</table>

$ 1,180,910 $ 1,848,077 $ 1,410,127 $ 4,439,114 $ 3,166,048 $ 1,006,745 $ 4,172,793 $ 8,611,907

See Notes To Financial Statements.
Patient-Centered Outcomes Research Institute

Notes To Financial Statements

Note 1. Nature Of Activities And Significant Accounting Policies

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by federal law (42 U.S.C. 1301 et seq.) in 2010 to “assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis.” PCORI also is charged with disseminating the results of that research, focusing on “health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items” studied.

PCORI is a 501(c)(3) non-profit corporation, governed by a 21-member multi-stakeholder Board of Governors, including 19 members appointed by the Comptroller General of the United States and the Directors of the Agency for Healthcare Research and Quality (AHRQ) and National Institutes of Health (NIH). By law, the Comptroller General 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). $1.26 billion was appropriated for Patient-Centered Outcome 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 appropriations were $120 million and $120 million for fiscal years 2012 and 2011, respectively (See Note 2).

The Secretary of the Treasury also provides for transfers to the PCORTF from the Federal Hospital Insurance (FHI) Trust Fund and the Federal Supplementary Medical Insurance (FSMI) Trust Fund in proportion to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund. In FY 2012, the PCORTF received an amount equal to $1 multiplied by the average number of individuals entitled to benefits under part A or enrolled under part B of title XVIII during such fiscal year. For each calendar year thereafter, 2013 through 2018, the PCORTF will receive an amount equal to $2 multiplied by the average number of individuals entitled to benefits under part A, or part B, of title XVIII during such fiscal year. For calendar year 2014 and thereafter, these amounts will be adjusted for increases in healthcare spending. The increase will be the product of the sum of such dollar amount for the previous fiscal year plus an amount equal to the product of such dollar amount for the previous fiscal year, multiplied by the percentage increase in the projected per capita of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

The transfer amounts in FY 2012 are based on the published Mid-Session Review of the President’s Budget.

In calendar year 2013 and beyond, the PCORTF will begin receiving the funding from the fees that will be imposed on certain health insurance and self-insured health plans. These fees will also be adjusted for increases in healthcare spending. The increase will be the product of the sum of such dollar amount for the previous fiscal year plus an amount equal to the product of such dollar amount for the previous fiscal year, multiplied by the percentage increase in the projected per capita of National Health Expenditures as most recently published by the Secretary before the beginning of the fiscal year.
Patient-Centered Outcomes Research Institute

Notes To Financial Statements

Note 1. Nature Of Activities And Significant Accounting Policies (Continued)

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, 2012 and 2011.

Property and equipment: Property and equipment at December 31, 2012, consisted of leasehold improvements, furniture and fixtures, and software. Purchases of property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives of four to eight years. It is the policy of PCORI to capitalize property and equipment purchases greater than $500. PCORI amortizes leasehold improvement costs over the term of PCORI’s lease, or the useful life of the improvement, whichever is shorter.

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. In accordance with the legislation, beginning in calendar year 2012, the Secretary of the Treasury provided for transfers to the PCORTF from the Federal Hospital Insurance (FHI) Trust Fund and the Federal Supplementary Medical Insurance (FSMI) Trust Fund in proportion to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund. The transfer amounts are based on estimate and they are subject to a true-up when the final calculations become available. The transfers are deemed to be earned and are recorded as revenue on a cash basis in the period received or adjusted.

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) and the applicable income tax regulations of the District of Columbia, except for unrelated business income. No provision for income taxes was required for the years ended December 31, 2012 and 2011, as PCORI had no unrelated business income.

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.
Notes To Financial Statements

Note 1. Nature Of Activities And Significant Accounting Policies (Continued)

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.

Use of estimates: The preparation of financial statements requires management to make estimates and assumptions 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.

Audit requirements: PCORI received funding in calendar year 2012 from direct appropriation and transfers from the Federal Hospital Insurance (FHI) Trust Fund and the Federal Supplementary Medical Insurance (FSMI) Trust Fund. As such, PCORI is subject to financial reporting and compliance and other matters audits in accordance with Government Auditing Standards.

Subsequent events: PCORI evaluated subsequent events through March 12, 2013, 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, 2012 and 2011, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
<td>$158,078,971</td>
<td>$49,638,865</td>
</tr>
<tr>
<td>Federal appropriations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Fiscal Year 2012 Appropriation</td>
<td>-</td>
<td>150,000,000</td>
</tr>
<tr>
<td>Government Fiscal Year 2013 Appropriation</td>
<td>150,000,000</td>
<td>-</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(30,000,000)</td>
<td>(30,000,000)</td>
</tr>
<tr>
<td>Transfers from FSMI, November 2012</td>
<td>27,265,000</td>
<td>-</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(5,453,000)</td>
<td>-</td>
</tr>
<tr>
<td>Transfers from FHI, November 2012</td>
<td>24,730,000</td>
<td>-</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(4,946,000)</td>
<td>-</td>
</tr>
<tr>
<td>Interest earned</td>
<td>48,461</td>
<td>24,106</td>
</tr>
<tr>
<td>Less draws by PCORI</td>
<td>(38,108,196)</td>
<td>(11,584,000)</td>
</tr>
<tr>
<td></td>
<td>$281,615,236</td>
<td>$158,078,971</td>
</tr>
</tbody>
</table>

By law PCORI is prohibited from making investments. Amounts held by PCOR Trust Fund are placed in market-based overnight Treasury securities. These are Treasury securities whose interest rates or prices are determined based on the interest rates or prices of Treasury-related financial instruments issued or trading in the market, rather than on the interest rates or prices of outstanding marketable Treasury securities. This type of security is bought and redeemed at par, and pays interest on maturity. The fair market value of this type of security is par.
Patient-Centered Outcomes Research Institute

Notes To Financial Statements

Note 3. Property And Equipment

Property and equipment and accumulated depreciation at December 31, 2012 and 2011, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leasehold improvements</td>
<td>$1,660,616</td>
<td>$159,153</td>
</tr>
<tr>
<td>Software development</td>
<td>568,984</td>
<td>-</td>
</tr>
<tr>
<td>Furniture, fixtures, and equipment</td>
<td>774,674</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,004,274</strong></td>
<td><strong>159,153</strong></td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(348,109)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Property and Equipment</strong></td>
<td>$2,656,165</td>
<td>$159,153</td>
</tr>
</tbody>
</table>

PCORI took possession and began construction on permanent office space in December, 2011. Occupancy of the leased premises began in March, 2012.

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. The lease was amended in March 2012 to include more space. Per the terms of the lease, the landlord will abate half of the rent for six months during the first three years of the lease. The landlord also contributed $835,227 to be used towards tenant improvements.

Future minimum rental payments applicable to the lease at December 31, 2012, are as follows:

<table>
<thead>
<tr>
<th>Years Ending December 31</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$707,952</td>
</tr>
<tr>
<td>2014</td>
<td>803,701</td>
</tr>
<tr>
<td>2015</td>
<td>823,773</td>
</tr>
<tr>
<td>2016</td>
<td>844,337</td>
</tr>
<tr>
<td>2017</td>
<td>865,401</td>
</tr>
<tr>
<td>2018 – 2020</td>
<td>1,948,740</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$5,993,904</td>
</tr>
</tbody>
</table>

PCORI has operating leases for several of its copiers. Future minimum rental payments are as follows:

<table>
<thead>
<tr>
<th>Years Ending December 31</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$8,160</td>
</tr>
<tr>
<td>2014</td>
<td>8,160</td>
</tr>
<tr>
<td>2015</td>
<td>6,120</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$22,440</td>
</tr>
</tbody>
</table>
Patient-Centered Outcomes Research Institute

Notes To Financial Statements

Note 5. Financial Risks And Uncertainties

The PCORTF is funded by appropriation of the U.S. Government through September 30, 2019; however, on March 1, 2013, the sequestration as required by the Budget Control Act of 2011 (BCA) and pursuant to section 251A of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended (BBEDCA), went into effect. The sequestration imposes a number of percentage based federal spending reductions, including a reduction in funding to the PCORTF. Because of the uncertainty in estimating the total revenues from all sources from the Federal government in FY2013 at this time, the actual impact on the availability of funding to PCORI is unknown.
Patient-Centered Outcomes Research (PCOR) Definition

PCOR helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare 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.