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

PCORI’S 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.
“I will never again be able to conceptualize or implement a research project without the input of these important stakeholders.”

Supriya Mohile, MD, MS
Director of the Geriatric Oncology Clinic University of Rochester, PCORI awardee

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A Year of Growth and Focus

For those of us privileged to have served on PCORI’s Board of Governors since it was established in 2010, it’s a pleasure to look back at FY 2014 and see how much we’ve grown as a major national research funder.

This was the year that the Board approved PCORI’s Strategic Plan, which not only outlines the long-term goals for all of the work we do but also provides a clear statement of the principles and values that drive us as we seek to improve health and patient outcomes. Every time we and our Board colleagues meet to hear about PCORI’s progress in carrying out its formidable set of current tasks or to consider an exciting new initiative, we ensure that we’re all remaining true to our strategic goals.

In the past four years, we’ve built a foundation and processes that now enable us to vigorously and effectively pursue our first strategic goal—to substantially increase the quantity, quality, and timeliness of useful, trustworthy information available to support health decisions. Last year, we began to put in place the processes and tools needed to advance our second goal—to speed the implementation and use of patient-centered outcomes research evidence. As a result, we’re seeing promising signs every day that we’re making progress in achieving our third goal—to influence clinical and healthcare research funded by others to be more patient-centered.

We’re excited about the organization we’ve established, the research projects we’ve funded to date, and the important new initiatives we’ll pursue in the year ahead. We look forward to sharing the results of our Pilot Projects—our first funded studies—and, soon after that, the results of our initial primary comparative clinical effectiveness research projects.

All these achievements, and the many others that we outline in the pages that follow, are a direct result of the strong working relationship that has developed between PCORI and its stakeholders. Creating a major national research funder from scratch is a substantial challenge, and all of us on the Board are continually impressed by how effectively the staff carries out its mission.

A final note: on September 30, 2014, Steve Lipstein stepped down from his Board vice chairperson duties and was succeeded by Kerry Barnett, JD, executive vice president and chief legal officer at Cambia Health Solutions. Steve’s leadership and vision have been central to the progress PCORI has made. We’re fortunate both that he’ll remain on the Board and that Kerry, who has similarly strong vision and expertise, will step into the vice chairperson role.

We look forward to guiding PCORI as it continues to fund studies that will provide strong evidence to aid decision making across the healthcare community and improve care for conditions that impose a high burden on individuals and the healthcare system.

Grayson Norquist, MD, MSPH
Vice-Chairperson, Emory University Department of Psychiatry and Behavioral Sciences, and Chief of the Psychiatry Service at Grady Health System, Atlanta, Georgia
Chairperson, PCORI Board of Governors

Steven Lipstein, MHA
President and Chief Executive Officer of BJC HealthCare, St. Louis, Missouri
Vice Chairperson (outgoing), PCORI Board of Governors*

Kerry Barnett, JD
Kerry Barnett, JD, Executive Vice President and Chief Legal Officer at Cambia Health Solutions, Portland, Oregon
Vice Chairperson (incoming), PCORI Board of Governors

* On September 30, 2014, Steve Lipstein stepped down as Vice Chairperson, but he remains on the Board of Governors.
Setting the Stage for Research
Results that Can Make a Difference

This has been a year of major achievements for PCORI as we solidified our position as the nation’s leader in funding patient-centered comparative clinical effectiveness research (CER). We’re proud of our work to date and excited about the future. As we reflect on the past year, four areas are worth special note.

A firm base for “research done differently.” We continue to refine our approach to meeting our mandate to conduct CER in a way that will yield results useful and meaningful to patients and those who care for them. PCORI has distinguished itself by its dedication to engaging stakeholder communities in identifying and implementing the questions and studies most likely to produce useful information for real-world care. This is the essence of patient-centered outcomes research (PCOR).

A growing research portfolio based on that foundation. In FY 2014, we approved $397.8 million in funding for 163 patient-centered CER and related projects. This brings our complete research portfolio to 360 projects in 39 states and $671 million in support. Most of these projects are studying high-impact questions that matter to patients and those who care for them; others are further developing the methods used in PCOR or learning how to help communities prepare to participate in such research.

PCORnet. We made substantial progress in developing PCORnet, the National Patient-Centered Clinical Research Network. This potentially transformative initiative seeks to improve the nation’s ability to conduct a range of efficient clinical outcomes studies. PCORnet is designed to enable practice-changing research by harnessing the vast data locked within health systems and clinical settings, as well as information and experiences reported by patients themselves. PCORnet is unprecedented in its scope and its commitment to seeing that patients help set the rules by which the network operates. We provided approximately $104 million to support the development into PCORnet of 29 clinical and patient-run data networks.

A clear and ambitious plan for future research. We continued to focus our research portfolio on high-impact research topics that our stakeholders tell us are important and address critical evidence gaps. This included a new initiative to fund pragmatic clinical studies, large projects usually conducted in routine clinical settings, involving major national stakeholder organizations and intended to provide definitive information that can be directly adopted in practice. This past year also saw significant improvements in our operational capacity and refinements in our Board governance structure to fully align our work with our strategic plan. And we made progress in developing the processes needed to ensure that we peer-review the results of the primary studies we fund, make research results widely available, and regularly monitor the impact of our work.

We know we have more to do. In the year ahead, we’ll further sharpen our process for prioritizing research topics for funding and continue to focus our research portfolio. We will also implement our process for peer review and public release of findings and our related plan for disseminating the results to promote their update in practice. We have a clear path for embracing these tasks and look forward to working with the healthcare community as we continue to support a patient-centered approach to healthcare research.

Joe Selby, MD, MPH
Executive Director

Jean Slutsky, PA, MSPH
Chief Engagement and Dissemination Officer

Bryan Luce, PhD, MS, MBA
Chief Science Officer

Regina Yan, MA
Chief Operating Officer
In FY 2014, with the foundational elements for funding patient-centered comparative clinical effectiveness research (CER) in place, PCORI focused its efforts on refining our research portfolio, guided by a newly approved strategic plan and a core commitment to engaging with patients and other healthcare stakeholders in all of our work.

Our research portfolio grew significantly, as our Board of Governors approved funding for 163 new CER and related projects. We continued to sharpen our focus on studies targeting specific high-burden conditions and on answering research questions that matter most to patients, caregivers, clinicians, and other healthcare stakeholders. We refined the process by which we select high-impact topics and added funding for larger, longer-term projects conducted in real-world settings to help patients and clinicians answer practical questions about care options.

With an eye toward enhancing the nation’s infrastructure to conduct the type of research we were created to fund, we established and provided initial support for the development of the National Patient-Centered Clinical Research Network (PCORnet), a national clinical data initiative designed to improve the pace, agility, and patient-centered nature of clinical outcomes research. We also continued to advance the development and use of high-quality research methods. We saw the first studies we funded, a series of Pilot Projects designed to develop and evaluate methods and strategies to advance patient-centered outcomes research (PCOR), move forward into data collection and preliminary analysis.

We made substantial advances in how we engage...
National Institute on Aging announces awardee for $30 million PCORI-funded study on preventing fall-related injuries in older adults

JUNE

Proposal for peer review and release of primary research findings posted for public comment

Board approves $102 million for 46 studies

AHRQ announces awardee for $20 million PCORI-funded study on uterine fibroids treatment

SEPT 2014

Board approves topic for first PCORnet clinical trial: assessing optimal dose of aspirin for patients with heart disease

Board approves $54.8 million in awards to fund 33 studies

JULY

patients and other stakeholders in our selection of research topics to fund, developed practical tools to better guide applicants on what we mean by engagement, and strengthened oversight of engagement practices in the studies we support. We also advanced a variety of initiatives, including a new awards program, designed to build a national community of patients, stakeholders, and researchers with the expertise and passion to participate in PCOR and create partnerships that lead to high-quality research proposals.

We substantially expanded our efforts to rigorously evaluate whether our work, including our requirements for engagement of patients and stakeholders in the research, is advancing our mission, meeting strategic goals, and helping to influence the research enterprise more broadly to become more patient-centered.

We realigned our Board governance and our operations in accordance with our strategic plan, while improving the operational efficiency of our growing staff and the services we provide to applicants and awardees.

Finally, as we looked toward the completion in 2015 of our first primary research projects, we began to lay the groundwork for the process of ensuring the validity of our funded studies and making their results widely available to patients, clinicians, and the general public in forms they can use to improve healthcare decision making.
CORI’s research portfolio grew substantially in FY 2014, guided by our strategic plan and building on a strong foundation established to fund comparative clinical effectiveness research (CER) guided by patients and other healthcare stakeholders. At the same time, we continued sharpening our focus on funding studies targeting specific high-burden conditions, including a series of larger, longer-term projects designed to be conducted in real-world settings and help patients and clinicians answer practical questions about care options. All of this work advanced the National Priorities for Research and Research Agenda adopted by our Board of Governors in May 2012.

We improved our processes for selecting research topics for potential funding, application review, portfolio management, and evaluation. Because our first primary research projects will be completed in 2015, we began developing a process for peer-reviewing that research and making findings publicly available in a form and format useful to patients, clinicians, and others.

And we took a major step forward in our pioneering initiative to improve the nation’s capacity to conduct patient-centered outcomes studies more efficiently and less expensively, approving initial awardee funding to advance PCORnet.

Expanding and Shaping Our Portfolio
During FY 2014, we committed $304.3 million in funds for research studies. As in the past, much of this was made available through broad calls for the research community’s best ideas for patient-centered CER projects across a wide range of topics. We completed three cycles of broad calls for funding through PCORI Funding Announcements (PFAs) issued under our five National Priorities for Research, with our Board approving 121 awards totaling $196.5 million in support.
We also began to focus more of our funding opportunities on targeted high-burden topics, an evolution in our portfolio planned since our first rounds of funding. Initially, to jump-start our focused agenda, our Board identified a set of five high-priority topics. Currently, topics are selected through a prioritization process (see page 10) that relies on our multi-stakeholder advisory panels to help us select and refine the patient-centered research questions most likely to have an impact on practice if addressed through PCORI-funded studies.

We committed $107.8 million in targeted funding for 13 projects. These include a large-scale project on effectiveness of transitional care and a group of projects on treatment options for African Americans and Hispanics/Latinos with uncontrolled asthma. As part of this effort, we also developed several important collaborations with top federal research funders. The first was with the National Institute on Aging of the National Institutes of Health (NIH) for a five-year, $30 million trial of a comprehensive program to reduce injuries from falls in older adults. The second was with the Agency for Healthcare Research and Quality (AHRQ) for a five-year, $20 million project to evaluate different treatment strategies for uterine fibroids. A third collaborative project, also with NIH, examining how best to reduce disparities in hypertension treatment outcomes in high-risk groups, was in development at year’s end.

Our Pragmatic Clinical Studies Initiative
As an extension of our effort to sharpen our research portfolio, we launched the Pragmatic Clinical Studies initiative to establish a focused set of larger, longer-term real-world CER projects designed to produce evidence that can be quickly used to significantly improve treatment of high-burden conditions.

Unlike traditional randomized trials, pragmatic studies address practical questions faced by patients, clinicians, and other decision makers, and tend to involve patients and care interactions in typical hospital and other clinical settings, rather than in specialized research settings. These studies typically include a greater diversity of patients, including those with multiple health problems.

### About Pragmatic Clinical Studies

These are studies involving large numbers of patients designed to determine which of two or more healthcare options work best for patients, given their preferences and circumstances.

Studies must involve clinician, patient, and other stakeholder groups as partners and can address:

- Prevention, diagnosis, treatment, or management of a disease or symptom
- Improvement of healthcare systems—level approaches to managing care
- Elimination of health or healthcare disparities

### Our National Priorities for Research and Research Agenda

<table>
<thead>
<tr>
<th>Priority Area</th>
<th>Description</th>
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<tbody>
<tr>
<td>Assessment of Prevention, Diagnosis, and Treatment Options</td>
<td>Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.</td>
</tr>
<tr>
<td>Improving Healthcare Systems</td>
<td>Comparing health system—level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.</td>
</tr>
<tr>
<td>Communication and Dissemination Research</td>
<td>Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision making between patients and their providers.</td>
</tr>
<tr>
<td>Addressing Disparities</td>
<td>Identifying potential differences in prevention, diagnosis, or treatment effectiveness, or preferred clinical outcomes across patient populations and the health care required to achieve best outcomes in each population.</td>
</tr>
<tr>
<td>Accelerating Patient-Centered Outcomes Research and Methodological Research</td>
<td>Improving the nation’s capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients, and other stakeholders to participate in this research.</td>
</tr>
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See the complete National Priorities for Research and Research Agenda at [www.pcori.org/national-priorities](http://www.pcori.org/national-priorities)
Although these heterogeneous populations can make the data analyses more complex, they also better reflect actual clinical populations and care situations, making the results more useful to clinicians and more applicable to the broad range of circumstances of American patients.

We issued three PFAs in FY 2014 under this new initiative, offering a total of up to $270 million in support of large patient-centered studies comparing two or more interventions in real-world settings. The announcements invited researchers proposing studies to attend especially to the Institute of Medicine’s Initial National Priorities for Comparative Effectiveness Research, AHRQ’s Future Research Needs projects, and PCORI’s 19 high-priority topics identified by our multi-stakeholder advisory panels. Initial awards were scheduled to be announced in February 2015.

As in all our funding, we require that each research team funded under this initiative partner with relevant patients, clinicians, and other stakeholders that strongly endorse the proposed study. Our Pragmatic Clinical Studies funding announcements included a specific requirement for partnering with relevant patient, professional, or healthcare payer or purchaser organizations. Throughout the study, these individual and organizational stakeholder partners guide the teams to make research questions and outcomes relevant to clinical practice and increase the likelihood that the findings will be disseminated and implemented.

Investing in PCORnet, the National Patient-Centered Clinical Research Network

FY 2014 was a year of substantial progress for PCORnet, the PCORI-funded national health data research infrastructure project designed to improve the pace, agility, and patient-centered nature of clinical outcomes research.

Our Board approved $93.5 million in initial funding for 29 research networks to develop their capacity to participate in PCORnet, 11 Clinical Data Research Networks, or CDRNs, which are based in large healthcare systems, and 18 Patient-Powered Research Networks, or PPRNs, which are operated and governed by groups of patients and their partners and are focused on a particular condition. The Board previously had awarded a contract for the PCORnet Coordinating Center, which provides administrative coordination and technical support for key network-building
tasks, including data resource development, internal communication, and organizational infrastructure.

PCORnet's bold vision is to harness the power of information in electronic health records and claims databases, as well as that reported by patients themselves, to conduct research that more efficiently and less expensively answers questions that matter most to patients and those who care for them.

In its first year, PCORI program staff and PCORnet awardees worked to establish a critically important culture of collaboration, bringing together researchers, patient partners, and the Coordinating Center to set the tone and chart the course for PCORnet's future. A key focus was on how to make real the project's core commitment to engaging patients in the policies and processes under which PCORnet will operate, including safeguards for data privacy, security, and use.

Awardees met an array of critical milestones, including developing the PCORnet Patient Council, a key advisory body; establishing governance structures within each participating network that included patients in leadership or advisory roles; and establishing the PCORnet Common Data Model Version 1.0, which enables the rapid and efficient conduct of observational and interventional studies.

Toward the end of the year, PCORI's Board approved the topic for PCORnet's first demonstration project, determining the optimal maintenance aspirin dose for patients with coronary artery disease. Among suggestions from the partner networks, this topic was ranked highest by PCORI's multi-stakeholder Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options. This trial will help network partners assess the interoperability and security of their data and demonstrate the capacity of PCORnet to conduct research efficiently while maintaining high standards.

**PCORnet’s Pilot Projects—On the Road to Completion**

During FY 2014, many of our 50 Pilot Projects—which address evidence-based methods and strategies to advance patient-centered outcomes research (PCOR)—transitioned from their preparatory stage into data collection and preliminary analysis. The project teams also participated in a learning network, with monthly webinars and an online communication platform, to facilitate knowledge synthesis and sharing, foster new collaborations, and accelerate methods for PCOR. In March, the researchers and their stakeholder partners met in Washington, DC, where they brainstormed communication and dissemination strategies and discussed future research opportunities. The Pilot Project teams have also joined in eight cross-project collaborations focused on improving processes for
“Isn’t the patient—the one with the disease—the most knowledgeable about what needs to be studied and how? And what about the clinician—can she be involved, too, in coming up with research questions and implementing the results? No doubt, the researcher has irreplaceable expertise, but aren’t the patient and clinician also vital partners in the process?”

Leana Wen, MD, member, PCORI Advisory Panel on Patient Engagement

Evidence to Action Networks
To facilitate cross-learning between research teams with related projects, we introduced the concept of Evidence to Action Networks, a series of communities connecting awardees with each other as well as with the end users of the research projects we’re funding. The first of these is organized around our asthma portfolio. The networks are designed to advance opportunities for awardees to share experiences and promising practices as well as allow for exchanges between awardees and a range of stakeholders—including payers, purchasers, employers, clinicians, professional societies, policy makers, and training institutions—to support dissemination and implementation of important findings.

Advancing Development and Use of Our Methodology Standards
During the year, we continued to carry out our commitment to developing and improving the science and methods of patient-centered CER. This critical focus is noted in both our authorizing law and our strategic plan as a path to producing more valid, trustworthy, and useful information that will lead to better-informed health and healthcare decisions and, ultimately, improved patient outcomes.

Early in the year, our Board accepted the revised version of the PCORI Methodology Report, which provides context for the 47 methodology standards previously adopted by the Board. Meanwhile, our Methodology Committee, which developed the initial standards with extensive stakeholder input, began seeking input from PCORI’s broad stakeholder community for opportunities to both refine our current standards and identify areas for development of new standards. The committee focused on two new areas—study designs using clusters, and complex interventions—but remained interested in additional gaps that need to be addressed. To advance this process, the committee examined standards of other organizations and invited stakeholders to suggest topics for new standards through PCORI’s website. The PCORI Methodology Report and Standards may be found at www.pcori.org/methodology.

PCORI staff also accelerated the process of assessing the use and impact of the standards, starting with rigorous and comprehensive monitoring by Program Officers of adherence to the standards by our awardees in the projects we fund. An examination of the applications across three funding cycles gave encouraging results: of the CER studies funded, adherence to the relevant and applicable methodology standards was about 90 percent. We plan to continue to work with applicants to ensure they meet all applicable standards by award completion. We held webinars to introduce the standards to different stakeholder communities and began developing a set of training curriculums tailored to different components of the research community.

We also started developing a plan to drive dissemination of our methodology standards, promote their uptake, and encourage other organizations to implement similar standards. To track progress, we counted citations in the scientific literature of the PCORI Methodology Report and Methodology Standards; there were nearly 150 citations by year’s end.

Refining Our Process for Selecting Topics for Targeted Research Funding
As our research portfolio continued to evolve to become more targeted, we refined the process by which we identify research questions that matter to patients, caregivers, clinicians, and other healthcare stakeholders.

We continue to gather suggestions from a wide
range of sources, screen them against eligibility criteria, and present selected topics to our multi-stakeholder advisory panels for further review and refinement. We added and refined the screening and prioritization criteria at each step. We also provided new opportunities for one of our Board strategy committees, which is made up of both Board and Methodology Committee members, to advise on the topics under consideration earlier in the process.

To ensure that our choice of targeted funding opportunities is informed and fully vetted by patients and other important stakeholders, our Engagement program began planning multi-stakeholder workshops oriented around potential topics for funding. During the year, our four initial advisory panels—one on Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Addressing Disparities; and Patient Engagement—met in person or via teleconference/webinar and reviewed dozens of topics for potential funding. We also established two new panels, as called for in our authorizing law, on Clinical Trials and Rare Disease. As the year ended, we were making plans for an additional panel on Communication and Dissemination Research.

Strengthening Our Merit Review Process
We made strides in FY 2014 in solidifying our Merit Review process, our multi-stakeholder approach to assessing the research proposals we receive. We built a team of 11 designated review program support staff, which oversaw the review of more than 1,000 applications, and established an easy-to-access reviewer database. We adapted our procedures to evaluate competitive Letters of Intent as well as full applications. We improved our reviewer training by providing online training and resources, as well as by holding online events. Topics included our Methodology Standards, human subjects protection, and conflicts of interest. We trained and provided feedback and guidance for 812 reviewers and 36 panel chairpersons. We also provided updated guidance to applicants on the process itself and human subjects protection requirements.

“This has given us an opportunity to be the creators of the [research] experience and the structure by working with, most importantly, other patients in the community.”

Ronnie Sharpe, Founder, CysticLife, PCORI Awardee
Strengthening Engagement as a Path to Better Research

From PCORI’s earliest days, we have been committed to meaningfully engaging patients and other stakeholders within the healthcare system (e.g., clinicians, hospitals and health systems, purchasers, payers, and industry) in all aspects of our work. This has meant involving them in determining what topics to study and which research projects to fund, developing and conducting the research itself, and ultimately disseminating the results. We believe this approach, which we call “research done differently” will make it more likely that the studies we fund ask the right questions and produce results that are relevant and useful to patients and clinicians and thus more likely to be adopted in practice. We also work to develop a nationwide community that is prepared to participate in the type of patient-centered comparative effectiveness research (CER) that we support.

Engaging an Informed Community

In the past year, we made substantial advances in how we engaged patients and other stakeholders in our selection of which research to fund, developed practical tools to better guide applicants in how to meet our requirements for including stakeholder partners in their research, and strengthened our oversight of stakeholder engagement in funded studies.

When we first invited research proposals, applicants regularly sought guidance about our engagement requirements. In response, we have revised our
funding applications, which now include links to more detailed explanations and examples of how stakeholders can participate in the planning and conduct of studies. We also revised the application forms in which we ask for biographical information so that they are more applicable to team members who are not traditional researchers.

Perhaps the most important tool we offer to researchers is the PCORI Engagement Rubric. We published the earliest version in February 2014. To create it, we analyzed our first 150 funded research proposals to identify promising engagement practices and used these examples to develop a tool that provides general guidance for applicants. This rubric was reviewed and revised by our Advisory Panel on Patient Engagement, vetted by PCORI staff, and incorporated into our funding announcements. It also guides our merit review process as well as much of our overall engagement work.

Applicant feedback suggests the rubric is effective in shaping and evaluating engagement by patients and other stakeholders in research proposals. But we realized that we needed additional mechanisms to ensure meaningful engagement throughout the conduct and dissemination of the research we fund. So we developed the concept of Engagement Officers, who would work in partnership with our scientific Program Officers to oversee specific projects within the portfolio. After pilot-testing the concept, we hired our first two Engagement Officers in mid-2014. In addition to monitoring engagement in funded projects and serving as important links between our Engagement and Science programs, these staff increasingly are sharing promising engagement practices with the broader healthcare community.

Extending the Community That Can Participate in Research
In FY 2014, we put in place and expanded programs that aim to build a national community of patients, stakeholders, and researchers who have the expertise and passion to participate in patient-centered research and to create partnerships within that community that lead to high-quality research proposals. This outreach includes two unique awards.

Eugene Washington PCORI Engagement Awards
Aim to increase the meaningful engagement of patients, caregivers, clinicians, and other healthcare stakeholders in the research process by expanding their knowledge and skills to participate in CER and patient-centered outcomes research (PCOR) and creating opportunities to build connections and share research findings. The awards also support meetings and conferences.

Awards of up to $250,000 per project

Pipeline to Proposal Awards
Enable individuals and groups that are not typically involved in clinical research to develop the means to produce community-led PCOR funding proposals that they could submit to PCORI or other research funders.

Three tiers of awards ranging from $15,000 to $50,000 per project

“Engagement increases the relevance of research to the larger agenda of improving population health. Rather than asking how patients and communities can get engaged in research, a better question is, how can we engage researchers in the work of communities?”

Steven H. Woolf, MD, MPH, and Alexander Krist, MD, Virginia Commonwealth University, PCORI awardees

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Our Eugene Washington PCORI Engagement Awards program was launched in February 2014 to support projects that lead to better integration of patients and other stakeholders in healthcare research. The program accepted applications in three categories—knowledge, training and development, and dissemination. In September, the program created a new category of awards to support meetings and conferences focused on patient-centered outcomes and CER. By the end of FY 2014, the Engagement Awards program had made 11 awards totaling nearly $2.2 million dollars, was evaluating additional letters of inquiry, and awaited proposals from previously accepted letters.

Our Pipeline to Proposal Awards program, a three-tiered initiative, aims to strengthen relationships
between researchers, patients, and stakeholders, particularly in communities that have been underrepresented in research, and build the capacity for community partnerships to create research questions and submit patient-centered outcomes research (PCOR) research proposals. The program made its first 30 awards, which were limited to the western United States. These Tier I awards fund community-building and engagement projects led by individuals and groups with healthcare research ideas and an interest in patient-centered research. We also laid the groundwork for opening up the funding opportunity throughout the country, and we prepared to launch the second tier of the awards in 2015. Those Tier II awards will fund projects that develop research capacity, create new partnerships, and build the infrastructure needed to conduct research.

In another outreach effort, the PCORI Matchmaking App Challenge encouraged developers to create ready-to-use web- or smartphone-based apps to facilitate links and spur partnerships between researchers and patients, caregivers, clinicians, and other stakeholders interested in health research. In September, we announced the three winners, who demonstrated their apps’ power to help people share advice, stories, and ideas for studies and promote collaboration on conditions of mutual interest.

PCORI’s Ambassador Program took off in FY 2014. This volunteer initiative unites patient and other healthcare stakeholders around the promise of PCOR. The program offers opportunities for training, partnership, and sharing knowledge with others who support PCORI’s mission. Ambassadors are committed to the PCOR engagement principles of reciprocal relationships, partnership, co-learning, trust, and transparency. By year’s end, 99 Ambassadors had
completed our multi-module Ambassador Program Training course and begun participating in an online community that connects them with each other and PCORI staff. The new Ambassadors took advantage of various opportunities, such as participating in technical-expert panels, PCORI workgroup meetings, and research projects.

As we have from the beginning, we remained focused on face-to-face and virtual meetings with stakeholders and stakeholder groups around the country, as well as in Washington, DC. Since our inception, this effort has included regional workshops in US census regions underrepresented in PCORI’s work. In these workshops, we inform researchers, patients, and other stakeholders about PCORI and learn about work going on in regional PCOR communities. In FY 2014, we held regional workshops in Albuquerque and Minneapolis. Follow-up surveys provided to attendees indicated that a large percentage of those attending later went on to apply for PCORI funding or identified other ways to become involved with our work. In addition, through our Speakers Bureau, PCORI staff made presentations to more than 100 audiences, and we hosted a series of webinars aimed at stakeholder communities.

We also began planning multi-stakeholder workshops to bring together our diverse communities to share their experiences and expertise on specific topics and to help us decide where to make high-priority research investments (see page 10).

**Setting the Groundwork for Disseminating Research Findings**
Dissemination of our research findings is one of the activities specified in our authorizing law. Because our first primary research projects are scheduled to be completed in 2015 (most of our Pilot Projects will be completed earlier), we began planning a comprehensive effort to provide study results to the healthcare community.
“The fact that PCORI really emphasizes working with community members and disseminating what we’re finding in a way that’s easy to understand puts a discipline to our work and makes sure that we are not only thinking about the research and this project but ... how it could have a real-life impact.”

Suzanne Pak, Director of Community & Behavioral Health, Korean Women’s Association

community and encourage the use of that information as appropriate. We are committed to enhancing awareness of evidence useful to individuals and organizations as they make health decisions, and to speeding the integration of this evidence into practice.

As a first step to putting knowledge gained from PCOR into practice, we began developing a process for peer-reviewing our primary research and making research findings publicly available in a format useful to patients, clinicians, and others. Our legislative mandate requires we perform these activities within a specific period. The Board approved a draft proposal, which was posted for public comment in September 2014.

We also produced an initial framework for further dissemination and implementation activity. Its main components are in the box at right.

We made plans to hold a workshop and invite public input, with the expectation of developing an action plan for dissemination and implementation in early 2015.

Communicating with Our Many Audiences
Digital communication remains the core of our promotion and outreach efforts. We completed a major website redesign in September. For the redesign, we asked representatives of our stakeholder groups what they’d find most useful in a new site. This led us to simplify how we organize content and provide more information about who we are, what we do, and how stakeholders can become involved in our activities. We made it easier for viewers to find and apply for our funding opportunities. We also made it easier for visitors to our website to find detailed information about our funded projects, including enhancing the site’s searching and filtering functions and linking to related articles in the scientific literature. We plan to add summaries of study results as they become available.

During the year, we substantially expanded our online and social media presence. Our website traffic exceeded our targets, recording a total of more than 700,000 visits, with about 460,000 unique visitors and more than 2.3 million page views. These counts superseded those of the previous year by 20 percent, 35 percent, and 6 percent, respectively. We also grew our opt-in email list to almost 17,000 names. We surpassed industry standards on both email open and click-through rates. Our Twitter following jumped to 5,135, an 80 percent increase over the previous year, and our cumulative reach on Twitter went up 40 percent, reaching 41.8 million. In addition, PCORI was mentioned in the general and trade media more than three times as often as in the previous year. In each quarter of 2014, we saw an increase in the number of journal articles by awardees or about PCORI or its work. Moreover, 82 journal articles cited or mentioned PCORI work.

DISSEMINATION AND IMPLEMENTATION FRAMEWORK

- Assessment, beginning with peer review, of whether a particular research finding is relevant to stakeholders and ready for use
- Identification of an audience for the new information and of partners for our dissemination efforts
- Determination of how to best make the evidence available to relevant stakeholders
- Development of a strategy to encourage adoption of a new health or healthcare approach
- Evaluation of the success of the dissemination and implementation activity
At PCORI, one of our core values is a commitment to evidence and evaluation of our work, then using the results to drive continuous process improvement. This past year, we developed a robust program to evaluate all aspects of our work and to begin making plans for assessing its impact. This included an examination of our research portfolio and associated processes as well as surveys of the healthcare community’s knowledge of and attitudes toward comparative effectiveness research (CER).

Implementing Our Strategic Plan
To evaluate its progress, an organization must be clear about where it intends to go. Like many large organizations with challenging and complex missions, we rely on a strategic plan, which was approved in November 2013 by our Board of Governors.

Our strategic plan identifies three primary goals that we must achieve to fulfill our mandate to fund and disseminate CER that results in better-informed health and healthcare decisions, improved care, and better outcomes.

**OUR 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 (PCOR) evidence
- **Influence** clinical and healthcare research funded by others to be more patient-centered

The plan provides a roadmap for the next several years. It identifies five broad areas, or strategic imperatives, that organize all our activities and lead us toward our goals.

Our plan also sets forth five core values—patient-centeredness, usefulness, transparency, inclusiveness, and evidence (reliance on the best science available and assessment of our work to improve it)—to which
we aim to adhere as good stewards of the resources provided to us. Our evaluation activities will help ensure that these core values permeate every aspect of our work.

To advise us on how best to measure and evaluate the effectiveness of our work—from the usefulness of the studies we fund to the extent to which the findings from these studies affect health decisions—we appointed the PCORI Evaluation Group. This task force held its kickoff meeting in December 2013. The group included members of our Board and Methodology Committee as well as PCORI staff and external advisors selected for their expertise in specific areas of evaluation research. The group considered plans for measuring progress toward our goals and our impact. Topics that received specific attention during these meetings included evaluation of data collection, merit review, engagement, and PCORnet.

With input from the PCORI Evaluation Group, we created the PCORI Evaluation Framework to guide our activities. This framework, which reflects our strategic plan, organizes the questions our stakeholders and staff have submitted about our work and describes how we will go about answering these questions. It indicates what approach we will take, what we will measure, and where we will obtain the necessary data.

The evaluation framework addresses how we conduct our day-to-day work, how we are progressing toward our strategic goals, and, ultimately, if and how the research we fund will make a difference for patients and the public overall. The framework will evolve along with our work because, even as we answer initial questions, new ones will arise.

We use a visual representation of metric tracking, or dashboard, for reporting quarterly to our Board on what we are learning and how we are incorporating our findings into our work. The dashboard includes a wide array of information, reflecting the diversity of our funding initiatives and the mechanisms we are employing to meet our strategic goals. In the past year, we worked to enhance the utility of this tool so that it can provide quick visual updates on our progress relative to targets for all key aspects of our work, including funds committed for external research, award rates, project milestones, portfolio composition, and project completion. The dashboard is available online, so everyone with an interest in our work can see our progress.

Supporting Our Review by the Government Accountability Office

According to PCORI’s authorizing law, the Comptroller General of the United States must review various aspects of PCORI’s processes and activities not less frequently than every 5 years. The first of these reviews by the Government Accountability Office (GAO) began in March 2014.

The GAO identified two primary questions for the review:

- To what extent has PCORI established research priorities and funded research in accordance with its legislative requirements?
- To what extent has PCORI established plans and undertaken efforts to evaluate the effectiveness of its work?

Evaluators met numerous times with different teams of PCORI staff during FY 2014. The topics discussed included advisory panels, research funding, merit review, PCORnet, evaluation, and dissemination. We gathered information from all parts of PCORI to respond to the evaluators’ requests. The GAO report on PCORI is due in March 2015.

Examining Our Portfolio

To guide funding decisions, we regularly examine our research portfolio, applications received, and how our
"When I mentor other investigators, they often think at first that PCORI can't possibly mean that patients and other stakeholders must be intrinsically involved throughout the research process. 'That's impossible,' they say. But I have to assure them, it can be done, and it does improve the research."

Debra Fiser, MD, professor in the Departments of Pediatrics, Anesthesiology, and Psychiatry at the University of Arkansas for Medical Sciences

work fits with that funded by others. We also study our application, review, and engagement processes to see how we are meeting our strategic goals in those areas.

In FY 2014, we intensified our evaluation of our research portfolio. We developed a process to describe and analyze the clusters of projects within our portfolio in terms of populations studied, therapeutic areas addressed, and intervention types. This enables us to work more closely with the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) to ensure that the work we fund complements and does not duplicate their research. These assessments suggested areas for further research both to fill remaining evidence gaps and to create a critical mass of evidence that informs clinical practice to improve patient-centered care. They also help us plan for disseminating PCORI-funded research to stakeholders.

In looking at our internal processes, we began evaluating the effectiveness of our processes for capturing stakeholder-recommended research topics. The evaluation team continued collecting information from applicants about their experience with our application process and the information we provided them about PCORI’s unique approach. For example, a survey asking about our funding announcements indicated that applicants saw improvement over several cycles. We also surveyed both applicants and reviewers to guide us in fine-tuning our merit review process.

We began an examination of the types of applications we receive and how they relate to the types of research that we fund. We also started systematically collecting information from awardees, including patient and other stakeholder research partners and the networks funded under the PCORnet initiative, to better evaluate the effect of including stakeholders in all aspects of research. The information will be used to identify and support promising engagement practices.

We also surveyed participants of our outreach and engagement programs and other activities to track their involvement in PCOR. We plan to use the results to improve effectiveness of events and understand the influence we are having on building a PCOR community.

Understanding Stakeholder Views
To assess different healthcare communities’ knowledge of and attitudes toward health research, CER, and stakeholder engagement in research, we surveyed researchers, patients, and clinicians. We also prepared a similar survey for researchers and started developing one for caregivers. Results of these surveys will be available in FY 2015.

To obtain additional information on the public’s awareness of, perceptions of, and interest in patient engagement in health research, we added survey questions to the Health Information National Trends Survey, which routinely collects nationally representative data about the American public’s use of cancer-related information. In addition, through focus groups and interviews, we began planning to collect from different stakeholder communities, such as payers, purchasers, and industry, opinions about PCORI’s progress and how PCORI’s work can be most useful to them.
This past year, we realigned our governance and operations as called for in our Strategic Plan, while improving the operational efficiency of our growing staff and improving the service we provide to our applicants and awardees.

Updating Our Governance
Our Board reorganized its committee structure in February 2014, approving amendments to PCORI’s bylaws to implement a revised governance structure that reconstituted committees to support the advancement of PCORI’s three strategic goals. The new structure consists of:

- The Science Oversight Committee focuses on our goal of producing quality, timely, usable, and trustworthy comparative research information.
- The Engagement, Dissemination, and Implementation Committee focuses on our goal of speeding the implementation and use of evidence.
- The Research Transformation Committee focuses on our goal of encouraging clinical and healthcare research, including research funded by others, to be more patient-centric by promoting open science, the development of transformative research platforms,
and the conduct of more patient-centric and methodologically rigorous research.

Additionally, the bylaws amendments reorganized several committees that address governance, finance, administration, and oversight matters. This reorganization affected the Finance and Administration Committee, the Governance Committee, and two subcommittees of the Governance Committee (the Audit and Conflict of Interest Subcommittee and the Executive Evaluation and Compensation Subcommittee).

The Board also withdrew the charters of the Communications, Outreach, and Engagement Committee; Program Development Committee; Nominating Committee; and Standing Committee on Conflict of Interest. These four committees had been superseded by new and revised ones.

Adapting as We Grow

As we expanded our research funding, engagement, and evaluation activities, we required more staff across our departments. In FY 2014, we augmented our staff, growing from 77 to 150 employees, with most of the increase on our Science team. We also succeeded in filling the last of our program director positions.

We recognize that providing responsive customer service is key to our continued success. In FY 2014, we saw organization-wide improvement in the services we provide to our applicants, awardees, and other stakeholders. One important measure of this commitment is the timely execution of contracts. In the last FY 2014 funding cycle, 88 percent of the projects met our goal of fully executing contracts within 90 days of the award announcement.

We also provided in-depth departmental training to improve communications both internally and externally. Satisfaction ratings of applicants and awardees who contacted PCORI improved dramatically. In addition, we created more-detailed application manuals and developed online training for applicants, merit reviewers, awardees, and advisory panels.

As outreach to applicants and reviewers, we held 27 webinars and sent broadcast emails providing resources, instructions, and other information. We also held two in-person workshops, attended by 350 research administrators and Principal Investigators from across the country. The workshops provided tools and guidance for developing applications and improving project performance. We used information garnered at these workshops to enhance our PFAs and online system.

Recognizing that the fastest way for a customer to find answers is to look online, we launched our new, self-service Help Center. It provides timely information and enables visitors to submit queries online. We also extended the availability of our telephone helpdesk to business hours year-round, with weekend availability immediately before application deadlines. We met our goal of responding to administrative inquiries within two business days and answering questions to our program staff within three business days. More than 90 percent of those using the service reported that they were satisfied with the phone help received.

“Just as much as the researcher’s voice needs to come through in the application, the patient’s voice needs to come through.”

Rebecca A. Aslakson, MD, PhD, Principal Investigator for Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families
After four years of foundational work and increasingly focused research funding, we look forward to 2015 as the year that will begin to show results and lay the groundwork for measurable impact.

**Reporting Initial Results of Our Funded Studies**

By the end of FY 2015, we expect all 50 of our Pilot Projects to conclude their period of performance. These studies, awarded in 2012 as a prelude to our funding of primary research, were designed to collect data that could be used to improve methods for engaging patients and other stakeholders in comparative clinical effectiveness research (CER) and for identifying areas for development. Awardees have been publishing initial findings in the peer-reviewed literature over the past year. We anticipate that, among the contracts from our other initial funding cycles, 24 infrastructure and 3 primary research projects will conclude periods of performance in FY 2015.

We will finalize and implement the processes mentioned earlier for peer review of our primary research and public release of our study results, as well as for broader dissemination of our work, with the goal of seeing them applied in practice as widely and effectively as possible.

After adoption by our Board of Governors, we will implement these activities as our existing primary-research awardees reach the end of their studies. We will include more details on these tasks in all future contracts to ensure that the quality and broad availability of our research results makes them useful for answering important questions of patients and other stakeholders.

Looking further ahead, we are planning a robust effort to encourage the healthcare community to take advantage of results from the research that we fund. In 2015, we expect to finalize a framework to identify the most effective ways for these research findings to reach and influence those who make healthcare decisions. We will also create a toolkit with action steps and worksheets that highlight important tasks and tradeoffs to consider in dissemination and implementation activities.

Because patients and other healthcare stakeholders have valuable knowledge and practical perspectives, their ongoing engagement is essential to planning and executing effective dissemination and implementation. The set of practices we highlight in the framework and toolkit should speed and enhance the use of patient-centered CER in decision making, thereby improving patient outcomes.

**Funding Pragmatic Clinical Studies and PCORnet Demonstration Projects**

We will continue to refine our research portfolio. We will still seek the research community’s best ideas through our broad funding announcements but reduce the amount of funding devoted to such projects. At the same time, we will focus on a selected but growing number of studies that seek to improve care for a series of conditions identified by our stakeholder...
community as imposing a high burden on individuals and the healthcare system.

This shift from broad calls for relatively small projects to more-targeted calls for large studies is a natural progression that reflects the guidance we've received from the healthcare community, as well as our ever-sharpening focus on defining what makes an effective CER question. We know studies asking the right questions are likely to yield findings that patients and those who care for them will put to use.

We plan to announce our first awards under our Pragmatic Clinical Studies initiative in early 2015 and plan at least three additional rounds of funding for these projects. This will represent the greatest allocation of our research funding in 2015 and beyond, providing the opportunity to support dozens of high-impact CER projects that could significantly enhance patient care.

This coming year will see us start to harness the potential of PCORnet, our collaboration of research networks based in both large health systems and patient groups. Our goal is to use the power of large sets of healthcare data, under policies developed with the help of patients, to enable more rapid and cost-effective clinical research. We are planning initial studies to test-drive the newly developed PCORnet infrastructure. We've already identified the first clinical trial we plan to conduct—a test to determine what dose of aspirin will best treat patients who have cardiovascular disease. We expect this study to get under way in the spring.

In 2015, we will also begin investigating how to ensure the PCORnet infrastructure thrives long term to continue supporting the studies needed to answer clinical questions that arise in real-world settings.

Measuring the Power of Engagement
As we continue to expand and refine the initiatives that we employ to engage stakeholders across the healthcare community, we will begin assessing the value and impact of these activities. We will also reach out to other organizations that fund patient-engaged research to establish a community that can address challenges and share best practices. Finally, we will begin documenting how PCORI is influencing others who fund or perform healthcare research.

We continue to employ Engagement and Pipeline to Proposal awards to ready communities to participate in patient-centered CER. We will hire more Engagement Officers to ensure the views of stakeholders effectively shape the projects we fund. We will host a gathering of professionals focused on patient engagement to spur interactions among organizations. We will also host gatherings of specific stakeholder groups, such as pharmacy benefit management organizations, the pharmaceutical and biologics industry, and the devices and diagnostics industry.

Our evaluation activities will continue to gather evidence on the value of including patients and other stakeholders in the research process. We will also compile examples of organizations that we have inspired to become more patient centered.

Planning for the Future
We enter FY 2015 proud of our position as the nation's leader in funding patient-centered CER, and excited about the research projects we're supporting and our plans for important new initiatives. We look forward to sharpening our focus as we continue to fund studies that will provide strong evidence to aid decision making and improve care for high-burden conditions. We are eager to begin disseminating important findings and working to promote their adoption in practice to improve care and health.

We thank all of our stakeholders for their participation, support, guidance, and patience in our important work of developing a patient-centered approach to efficient and effective health and healthcare research.
Telling the Stories of PCORI-Funded Research

We are always trying to show how PCORI-supported studies marry solid science with meaningful stakeholder engagement. Here are some examples from Research in Action on our website at www.pcori.org/research-action

To Fight Depression, Consider the Context

ROCHESTER, NY—Elaine Bell, a retired nurse and factory worker, thinks back to a difficult time—with miscarriages and a demanding work and home life—when a mental health crisis brought her to a psychotherapist. “She wanted to talk about my relationship with my husband, and I wasn’t ready to deal with anything but my losses. She didn’t let me go where I needed to go.”

Now, Bell is in a position to do something about it. As a partner in a PCORI-funded project, she has helped design a study to test what happens when vulnerable, troubled women are connected to people who are trained to help them help themselves.

Researchers are testing whether helping women with depression solve their most pressing problems leads to better mental health.

Home-based Care for Chronic Kidney Disease

ZUNI, NM—This scenic valley 150 miles west of Albuquerque, home to the Zuni people for thousands of years, is Ground Zero in an epidemic of chronic kidney disease.

Now, a PCORI-supported, community-based research project aims to bring a new approach to care for chronic kidney disease. It will test a program in which indigenous, Zuni-speaking community health workers bring care into patients’ homes, and patients receive intensive support to encourage adherence to medical treatment and healthy lifestyle changes. The project will compare participants receiving the home-based program with those receiving the usual care provided by physicians based at the Indian Health Service clinic located a couple of miles away.

Fighting Depression with the Power of Community

LOS ANGELES, CA—When Pluscedia Williams was growing up in the Compton neighborhood of Los Angeles, nobody talked about depression. So Williams had no name to give the problems that beset her as a young woman: crying, mood swings, not wanting to talk to anyone or even care for her baby.

Now, PCORI is helping to fund a project in which 85 percent of the clients are African American or Latino, and 65 percent have less than $10,000 a year in family income. The research expands on an earlier trial designed to increase availability of mental health information and services by helping existing organizations work together under one common strategy, including ways to provide therapy, case management, clinical assessment, medication management, and outreach.

Long-Term Nicotine Replacement Therapy for Smokers with Lung Disease

KANSAS CITY, KS—Bobby Young began smoking when he was 11. Over the years, he made attempts to quit, but the pull of cigarettes was too strong. He has been unable to work since having a heart attack and a stroke in 2010 but is still smoking two packs a day. “Quitting cold turkey is too daunting,” he says.

But now, in a PCORI-funded study, several hundred smokers with lung disease, including Young, are being randomly assigned to one of two groups. One group follows 12 weeks of conventional smoking-cessation counseling and 10 weeks of nicotine replacement therapy to support a planned quit attempt. The other group receives a year of combination nicotine replacement therapy plus five counseling sessions focused on gradually reducing smoking.
## FY 2014 and Projected FY 2015 Budget

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<thead>
<tr>
<th></th>
<th>2014 Actual</th>
<th>2015 Budget</th>
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<td><strong>OPERATING REVENUE</strong></td>
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<td><strong>PROGRAM EXPENSE</strong></td>
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<tr>
<td>Research Expense &amp; Engagement Awards</td>
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### 2014 Actual Distribution

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<td>Research Expense &amp; Engagement Awards</td>
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<td>Science/Program Dev &amp; Eval</td>
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<td>Contracts</td>
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<tr>
<td>Administrative</td>
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### 2015 Budget Distribution

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<td>Methodology Committee</td>
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<td>Science/Program Dev &amp; Eval</td>
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<td>Engagement</td>
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<td>Contracts</td>
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### 2014 Actual Research Funding

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<tr>
<td>Clinical Effectiveness Research Program</td>
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<tr>
<td>Improving Healthcare Systems Program</td>
<td>25%</td>
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<tr>
<td>Addressing Disparities Program</td>
<td>7%</td>
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<tr>
<td>Communications and Dissemination Program</td>
<td>2%</td>
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<tr>
<td>CER Methods and Infrastructure Program</td>
<td>35%</td>
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<tr>
<td>Unassigned</td>
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### 2015 Budgeted Research Funding Projections

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<th>Program</th>
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<td>Clinical Effectiveness Research Program</td>
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<td>Improving Healthcare Systems Program</td>
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<td>Addressing Disparities Program</td>
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<tr>
<td>Communications and Dissemination Program</td>
<td>13%</td>
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<tr>
<td>CER Methods and Infrastructure Program</td>
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BOARD OF GOVERNORS
As of December 31, 2014
Debra Barksdale, PhD, RN
Kerry Barnett, JD
Lawrence Becker
Francis S. Collins, MD, PhD
Allen Douma, MD
Alicia Fernandez, MD
Christine Goertz, DC, PhD
Leah Hole-Marshall, JD
Gail Hunt
Robert Jesse, MD, PhD
Richard Kronick, PhD
Harlan M. Krumholz, MD, SM
Richard E. Kuntz, MD, MSc
Sharon Levine, MD
Freda Lewis-Hall, MD
Steven Lipstein, MHA (Vice Chairperson)
Barbara J. McNeil, MD, PhD
Grayson Norquist, MD, MSPH (Chairperson)
Ellen Sigal, PhD
Harlan Weisman, MD
Robert Zwolak, MD, PhD

Methodology Committee
As of December 31, 2014
Naomi Aronson, PhD
Ethan Basch, MD, MSc
David Flum, MD, MPH
Cynthia Girman, DrPH
Steven Goodman, MD, MHS, PhD (Chairperson)
Mark Helfand, MD, MS, MPH
Robert Kaplan, PhD
Michael S. Lauer, MD
David O. Meltzer, MD, PhD
Brian S. Mittman, PhD
Sally C. Morton, PhD
Robin Newhouse, PhD, RN (Chairperson)
Neil R. Powe, MD, MPH, MBA
Sebastian Schneeweiss, MD, ScD
Mary Tinetti, MD
Clyde Yancy, MD, MSc

Committees
In February 2014, the Board of Governors implemented a governance transition, including restructuring some committees to align with PCORI's Strategic Plan.

Strategy Committees
As of December 31, 2014

Engagement, Dissemination, and Implementation Committee
Naomi Aronson, PhD
Debra Barksdale, PhD, RN (Chairperson)
Lawrence Becker
Allen Douma, MD
Gail Hunt
Robert Jesse, MD, PhD (Vice Chairperson)
Richard Kronick, PhD
Sharon Levine, MD
Brian S. Mittman, PhD

Research Transformation Committee
Kerry Barnett, JD
Francis S. Collins, MD, PhD
Allen Douma, MD
Steven Goodman, MD, MHS, PhD
Gail Hunt
Harlan M. Krumholz, MD, SM
Freda Lewis-Hall, MD (Chairperson)
Harlan Weisman, MD
Clyde Yancy, MD, MSc

Science Oversight Committee
Alicia Fernandez, MD
Christine Goertz, DC, PhD (Chairperson)
Leah Hole-Marshall, JD
Richard E. Kuntz, MD, MSc
Barbara McNeil, MD, PhD
Ellen Sigal, PhD
Robert Zwolak, MD, PhD
Robert Kaplan, PhD
Michael S. Lauer, MD

Board Committees
As of December 31, 2014

Finance and Administration Committee
Kerry Barnett, JD (Chairperson)
Lawrence Becker
Alicia Fernandez, MD
Robert Zwolak, MD, PhD

Governance Committee
As of December 31, 2014
Allen Douma, MD
Sharon Levine, MD
Steven Lipstein, MHA (Chairperson)
Grayson Norquist, MD, MSPH
Robin Newhouse, PhD, RN

Audit and Conflict of Interest Subcommittee
Kerry Barnett, JD
Lawrence Becker (Chairperson)
Robert Zwolak, MD, PhD (Vice Chairperson)

Executive Evaluation and Compensation Subcommittee
Kerry Barnett, JD
Lawrence Becker
Steven Lipstein, MHA (Chairperson)
Grayson Norquist, MD, MSPH

Other Committees
As of December 31, 2014

Selection Committee
Christine Goertz, DC, PhD (Chairperson)
Leah Hole-Marshall, JD
Alicia Fernandez, MD
Debra Barksdale, PhD, RN
Harlan M. Krumholz, MD, SM
Michael S. Lauer, MD
Contracts Management and Administration
Scott Soloman, MBA, MSE, Director, Contracts Management
Enas Areiqat, Contracts Manager, Post-Award
Ashton Burton, Contracts Specialist, Pre-Award
Kisha Curry, Senior Administrative Assistant
Rohan Dalvi, Contracts Support Systems Specialist
Iris Giggets, MSW, CRA, Contracts Associate, Pre-Award
Geri Guman, MBA, Senior Contracts Administrator, Post-Award
Shayan Hobbi, Contracts Coordinator, Post-Award
James Hulbert, Contracts Manager, Pre-Award
Kristen Metzger, MPA, MSCJ, Contracts Specialist, Pre-Award
Soknomtha Prum, MPH, Contracts Administrator
Brigette Scott, MA, Communications Manager
Ceresa Wilson, Contracts Specialist, Pre-Award

Finance
Pamela Goodnow, CPA, CGMA, Director
John Alzona, Senior Cost Accountant
Ryan Bresnahan, Senior Administrative Assistant
Kim Jackson, CPA, CGMA, MBA, Deputy Director, Controller
Marlis Manuel, Senior Staff Accountant
Tracey Marable, Accounts Payable Manager
Fiona McEachran, Project Coordinator
Thomas Ringwood, MS, CPCM, CPM, CCME, Procurement Manager
William Rochelle, Accounts Payable Specialist
Merenda Tate, MBA, MHRM, Assistant Controller, Treasury Options
Chao Wang, CPA, CGMA, MBA, Assistant Controller, Internal Controls

Human Resources and Administration
Mitchell Eisman, Director
James Hawkins, Administrative Services Manager
Brittany Jones, Administrative Services Specialist
Jamel Porter, Receptionist and Administrative Assistant
Bruce Sanders, Onsite Meetings and Administrative Coordinator
Rebecca Balaguer, Human Resources Coordinator
Tandrea Jones, Contract Recruiter
Carly Vieira, PHR, Human Resources Manager
Matthew Burruss, Specialist, Meetings Management

Information Technology
James Convery, MBA, Director
Osama Al-Kahily, Systems Analyst, IT
Paul Ashton, PMP Systems Project Manager
Matthew Campbell, Systems Support Specialist
Liue Girma-Neway, Systems Support Specialist
Julien Goichot, Database Administrator, IT
Travis Johnson, Systems Project Manager
Hans Lasway, MS, Systems Analyst, IT
Paul Moses, System Support Administrator
Shevonne Polastre, Business Analyst, IT
Taylor Reeh, Online/Internal Meeting Coordinator
Zanga Toure, Database Administrator, IT
Christine Tuyey, QA/QC Engineer, Development
Patient-Centered Outcomes Research Institute
FY 2014 Annual Report

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### August 2013 Cycle Contracts

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<tr>
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<th>Organization</th>
<th>Principal Investigator</th>
<th>Contract Amount</th>
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<tr>
<td>A Method for Patient-Centered Enrollment in Comparative Effectiveness Trials: Mathematical Equipoise</td>
<td>Tufts Medical Center</td>
<td>Harry Selker</td>
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<td>A Patient-Centered Strategy for Improving Diabetes Prevention in Urban American Indians</td>
<td>Stanford University School of Medicine</td>
<td>Randall Stafford</td>
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<td>A Multiple Sclerosis Patient-Powered Research Network</td>
<td>Accelerated Cure Project for Multiple Sclerosis</td>
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<td>A National Pediatric Learning Health System</td>
<td>The Children’s Hospital of Philadelphia</td>
<td>Christopher Forrest</td>
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<td>A P2ATH Towards a Learning Health System in the Mid-Atlantic Region</td>
<td>University of Pittsburgh</td>
<td>Rachel Hess</td>
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<td>Accelerating Data Value Across a National Community Health Center Network (ADVANCE)</td>
<td>Oregon Community Health Information Network</td>
<td>Jennifer DeVoe</td>
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<td>Addressing HIV Treatment Disparities using a Self Management Program and Interactive Personal Health Record</td>
<td>University of Rochester</td>
<td>Kevin Fiscella</td>
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<td>Advancing the Medical Care of Patients with PI by Creating a PPRN that Welds Personal Patient Information with Clinical Outcomes</td>
<td>Immune Deficiency Foundation</td>
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<td>ALD Connect</td>
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<td>University of South Florida</td>
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<td>Amplifying the Patient’s Voice: Person-Centered Versus Measurement-Based Approaches in Mental Health</td>
<td>UPMC Center for High-Value Health Care</td>
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<td>An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use</td>
<td>University of Florida</td>
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<td>Applying Methods of User-Centered Design to Achieve Patient-Centered Care</td>
<td>Universite Laval</td>
<td>Holly Witteman</td>
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<td>ARthritis Patient Partnership With Comparative Effectiveness Researchers (AR-PoWER PPRN)</td>
<td>Global Healthy Living Foundation</td>
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<td>Bringing I-PASS to the Bedside: a Communication Bundle to Improve Patient Safety and Experience</td>
<td>Boston Children's Hospital</td>
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<td>Clinic-Based vs. Home-Based Support to Improve Care and Outcomes for Older Asthmatics</td>
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<td>Comparative Effectiveness of Family Problem-Solving Therapy (F-PST) for Adolescent TBI</td>
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<td>Comparative Effectiveness of Postoperative Management for Degenerative Spinal Conditions</td>
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<td>Kristin Archer</td>
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<td>Computer-Administered Animation as a New Method for Measuring Young Children’s Health Outcomes</td>
<td>University of California Irvine</td>
<td>Sherrie Kaplan</td>
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<td>University of Arizona</td>
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<td>Creating a Patient-Centered Tool to Help Medicare Beneficiaries Choose Prescription Drug Plans</td>
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<td>Culturally Adapted Brief Motivational Intervention for Heavy Drinking Latinos</td>
<td>The University of Texas at El Paso</td>
<td>Craig Field</td>
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<td>Development and User Testing of a Decision Aid for Ventricular Assist Device (VAD) Placement</td>
<td>Baylor College of Medicine</td>
<td>Jennifer Blumenthal-Barby</td>
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<td>Development of Practical Outcome Measures to Account for Individual</td>
<td>Albert Einstein College of Medicine Yeshiva University</td>
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<td>Differences and Temporal Changes in Quality of Life Appraisal</td>
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<td>Empowering Patients and Families for Community-Driven Research: The Duchenne</td>
<td>Parent Project Muscular Dystrophy</td>
<td>Holly Peay</td>
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<td>Evaluating Observational Data Analyses: Confounding Control and Treatment</td>
<td>Brown University</td>
<td>Issa Dahabreh</td>
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<td>Seattle-King County Public Health Department</td>
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<td>Heart Health 4 Moms: Engaging Women with a History of Preeclampsia to</td>
<td>Brigham and Women's Hospital</td>
<td>Janet Rich-Edwards</td>
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<td>Improving Medication Adherence in the Alabama Black Belt</td>
<td>University of Alabama at Birmingham</td>
<td>Monika Safford</td>
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<td>ImproveCareNow: A Learning Health System for Children with Crohn’s Disease</td>
<td>Cincinnati Children’s Hospital Medical Center</td>
<td>Peter Margolis</td>
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<td>and Ulcerative Colitis</td>
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<td>Improving Patient Engagement and Understanding Its Impact on Research</td>
<td>Vanderbilt University Medical Center</td>
<td>Consuelo Wilkins</td>
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<td>Improving Post-Discharge Outcomes by Facilitating Family-Centered Transitions</td>
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<td>Samir Shah</td>
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<td>Improving the Effectiveness of Routine Surveillance Following Lung Cancer</td>
<td>The Alliance for Clinical Trials in Oncology Foundation</td>
<td>Benjamin Kozower</td>
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<td>Thomas Jefferson University</td>
<td>Ronald Myers</td>
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<td>Innovative Randomized Trial Designs to Generate Stronger Evidence about</td>
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<td>Michael Rosenblum</td>
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<td>Integrated Care and Patient Navigators for Latinos with Serious Mental</td>
<td>Illinois Institute of Technology</td>
<td>Patrick Corrigan</td>
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<td>University of California Los Angeles</td>
<td>William McCarthy</td>
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<td>Kaiser Permanente &amp; Strategic Partners Patient Outcomes Research To</td>
<td>Kaiser Foundation Research Institute</td>
<td>Elizabeth McGlynn</td>
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<td>Louisiana Public Health Institute</td>
<td>Thomas Carton</td>
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<td>Methods for Analysis and Interpretation of Data Subject to Informative</td>
<td>University of California San Francisco</td>
<td>Charles McCulloch</td>
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<td>Methods for Prioritizing Surrogate Desired Health Outcomes for Patients</td>
<td>University of Maryland Baltimore</td>
<td>Susan dosReis</td>
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<td>Mobile Application for Improving Symptoms and Adherence to Oral Chemotherapy</td>
<td>Massachusetts General Hospital</td>
<td>Joseph Greer</td>
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<td>in Patients with Cancer</td>
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<td>Modeling Strategies for Observational CER - What Works Best When?</td>
<td>University of Pittsburgh at Pittsburgh</td>
<td>Doug Landsittel</td>
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<td>Mood Patient-Powered Research Network</td>
<td>Massachusetts General Hospital</td>
<td>Andrew Nierenberg</td>
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### August 2013 Cycle Contracts (continued)

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<td>NephCure Kidney Network for Patients with Nephrotic Syndrome</td>
<td>Arbor Research Collaborative for Health</td>
<td>Elizabeth Cope</td>
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<td>Rainu Kaushal</td>
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<td>Optimizing Health Outcomes in Patients with Symptomatic Aortic Valve Disease</td>
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<td>James Brennan</td>
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<td>Optimizing Patient Engagement in a Novel Pain Management Initiative (OPEN)</td>
<td>Inflexxion, Inc.</td>
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<td>Parent-Centered Innovations to Improve Adherence in At-Risk Youth with Asthma</td>
<td>Children's Research Institute</td>
<td>Stephen Teach</td>
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<td>Patient Assisted Intervention for Neuropathy: Comparison of Treatment in Real Life Situations (PAIN-CONTROLS)</td>
<td>University of Kansas Medical Center</td>
<td>Richard Barohn</td>
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<td>Patient-Centered Approaches to Collect Sexual Orientation/Gender Identity Information in the ED</td>
<td>Brigham and Women's Hospital</td>
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<td>Patient-Oriented SCAlable National Network for Effectiveness Research (pSCANNER)</td>
<td>University of California San Diego</td>
<td>Lucila Ohno-Machado</td>
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<td>PPRN: A Networked Registry for All</td>
<td>Genetic Alliance, Inc.</td>
<td>Sharon Terry</td>
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<td>Peer-Driven Intervention as an Alternative Model of Care Delivery and Coordination for Sleep Apnea</td>
<td>University of Arizona</td>
<td>Sairam Parthasarathy</td>
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<td>Persons with Disabilities Generating Quality Metrics to Inform Integrated Care</td>
<td>Massachusetts General Hospital</td>
<td>Lisa Iezzoni</td>
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<td>Physical Therapy vs. Internet-Based Exercise Training for Patients with Knee Osteoarthritis</td>
<td>University of North Carolina San Francisco</td>
<td>Kelli Allen</td>
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<td>Preference and Effectiveness of Symptom Based Adjustment of Inhaled Corticosteroid Therapy in African American Children</td>
<td>Washington University in St. Louis</td>
<td>Kaharu Sumino</td>
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<td>Preparing Spanish-Speaking Older Adults for Advance Care Planning and Medical Decision Making</td>
<td>University of California San Francisco</td>
<td>Rebecca Sudore</td>
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<td>Promoting Informed Decisions about Lung Cancer Screening</td>
<td>University of Texas MD Anderson Cancer Center</td>
<td>Robert Volk</td>
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<td>Scalable Collaborative Infrastructure for a Learning Healthcare System</td>
<td>Harvard University Medical School</td>
<td>Kenneth D. Mandl</td>
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<td>Semiparametric Causal Inference Methods for Adaptive Statistical Learning in Trauma Patient-Centered Outcomes Research</td>
<td>University of California Berkeley</td>
<td>Alan Hubbard</td>
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<td>Susan Redline</td>
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<td>Smoking Cessation Versus Long-term Nicotine Replacement among High-Risk Smokers</td>
<td>University of Kansas Medical Center</td>
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<td>Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions</td>
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<td>The Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes (CHICAGO) Trial</td>
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<td>The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HiFF-BAC) for African Americans</td>
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## August 2013 Cycle Contracts (continued)

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## Winter 2014 Cycle Contracts

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<td>Larry Allen</td>
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<td>and their caregivers offered destination therapy for end-stage heart failure</td>
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<td>Adherence prediction algorithms to explain treatment heterogeneity and</td>
<td>Brigham and Women’s Hospital</td>
<td>Joshua Gagne</td>
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<td>Emory University</td>
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<td>Calmer Life: Treating Worry among Older Adults in Underserved, Low-</td>
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<td>Caring for the Whole Person: A Patient-Centered Assessment of Integrated</td>
<td>Providence Portland Medical Center</td>
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<td>Care Models in Vulnerable Populations</td>
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<td>Northwestern University at Chicago</td>
<td>Shyam Prabhakaran</td>
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<td>Danielle Lavallee</td>
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<td>Johns Hopkins University</td>
<td>Nancy Kass</td>
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<td>University of Pittsburgh at</td>
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<td>Extended Family Model of DSME to Reduce Disparities in a US Pacific</td>
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<td>Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care</td>
<td>Mount Sinai School of Medicine</td>
<td>Nina Bickell</td>
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<td>Catarina Kiefe</td>
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<td>Stakeholders’ Eyes</td>
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<td>Improving Methods for Linking Secondary Data Sources for CER/PCOR</td>
<td>Duke University</td>
<td>Sean O’Brien</td>
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<td>Improving Patient Quality of Life and Caregiver Burden by a Peer-Led</td>
<td>Pennsylvania State University</td>
<td>Nasrollah Ghaemrami</td>
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<td>Mentoring Program for Patients with Chronic Kidney Disease and Their Caregivers</td>
<td>Hershey Medical Center</td>
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<td>Informing Patient-Centered Care for People with Multiple Chronic</td>
<td>Johns Hopkins University</td>
<td>Cynthia Boyd</td>
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### Winter 2014 Cycle Contracts (continued)

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<tr>
<td>Informing Tobacco-Treatment Guidelines for African American Non-Daily Smokers</td>
<td>University of Kansas Medical Center Research Institute, Inc.</td>
<td>Nikki Nollen</td>
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<td>New Analytic Approach for Valid Comparative Effectiveness Research</td>
<td>University of Pennsylvania</td>
<td>Richard Tannen</td>
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<td>Patient and Provider Engagement and Empowerment Through Technology (P2E2T2) Program to Improve Health in Diabetes</td>
<td>The Regents of the University of California, Davis</td>
<td>Heather Young</td>
<td>$2,004,444.40</td>
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<td>Patient Centered Home Exercise Program for Peripheral Artery Disease</td>
<td>Northwestern University</td>
<td>Mary McDermott</td>
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<td>Prescription Opioid Management in Chronic Pain Patients: A Patient-Centered Activation Intervention</td>
<td>Kaiser Foundation Research Institute</td>
<td>Cynthia Campbell</td>
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<td>Taking Charge of Systemic Sclerosis: Improving Patient Outcomes Through Self-Management</td>
<td>University of New Mexico Health Sciences Center</td>
<td>Janet Poole</td>
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<td>Testing the Effectiveness of a Graphic Novel Health Education Curriculum for Patients with Addiction</td>
<td>Treatment Research Institute, Inc.</td>
<td>Adam Brooks</td>
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<td>The Comparative Impact of Patient Activation and Engagement on Improving Patient-Centered Outcomes of Care in Accountable Care Organizations</td>
<td>University of California Berkeley</td>
<td>Stephen Shortell</td>
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<td>The Effectiveness of Peer-to-Peer Community Support to Promote Aging in Place</td>
<td>University of Wisconsin Madison</td>
<td>Elizabeth Jacobs</td>
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<td>The Impact of Self-Management with Probiotics on Urinary Symptoms and the Urine Microbiome in Individuals with Spinal Cord Injury (SCI) and Spina Bifida (SB)</td>
<td>MedStar Health Research Institute</td>
<td>Suzanne Groah</td>
<td>$1,772,717.97</td>
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<td>The SEED Method for Stakeholder Engagement in Question Development and Prioritization</td>
<td>Virginia Commonwealth University</td>
<td>Emily Zimmerman</td>
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<td>Treatment Options for Depression in Patients Undergoing Hemodialysis</td>
<td>University of Washington</td>
<td>Rajnish Mehrotra</td>
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### Spring 2014 Cycle Contracts

<table>
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<th>Project Title</th>
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<tr>
<td>A Comparative Trial of Improving Care for Underserved Asian Americans Infected With HBV</td>
<td>Temple University</td>
<td>Grace Ma</td>
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<td>A Randomized Controlled Trial of Anterior Versus Posterior Entry Site for Cerebrospinal Fluid Shunt Insertion</td>
<td>Baylor College of Medicine</td>
<td>William Whitehead</td>
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<td>Active and Healthy Brotherhood: a Program for Chronic Disease self-Management for Black Men</td>
<td>Gramercy Research Group, LLC.</td>
<td>Melicia Whitt-Glover</td>
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<td>Acupuncture Approaches to Decrease Disparities in Outcomes of Pain Treatment- A Two Arm Comparative Effectiveness Trial (AADDOPt-2)</td>
<td>Albert Einstein College of Medicine</td>
<td>Diane McKee</td>
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<td>Aligning the Visit Priorities of Complex Patients and their Primary Care Providers</td>
<td>Kaiser Foundation Research Institute</td>
<td>Richard Grant</td>
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<td>Causal Analyses of Electronic Health Record Data for Assessing the Comparative Effectiveness of Treatment Regimens</td>
<td>Kaiser Foundation Research Institute</td>
<td>Romain Neugebauer</td>
<td>$1,031,693.86</td>
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<td>CHOosing Options for Insomnia in Cancer Effectively (CHOICE): A Comparative Effectiveness Trial of Acupuncture and Cognitive Behavior Therapy</td>
<td>University of Pennsylvania</td>
<td>Jun Mao</td>
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<td>Comparative Effectiveness of Rehabilitation Interventions for Traumatic Brain Injury</td>
<td>Ohio State University</td>
<td>Jennifer Bogner</td>
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<td>Comparative Efficacy of Therapies for Eosinophilic Esophagitis</td>
<td>Cincinnati Children’s Hospital Medical Center</td>
<td>Marc Rothenberg</td>
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<td>Comparing Mobile Health (mHealth) and Clinic-Based Self-Management Interventions for Serious Mental Illness: Patient Engagement, Satisfaction, and Outcomes</td>
<td>Dartmouth College</td>
<td>Dror Ben-Zeev</td>
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### Spring 2014 Cycle Contracts (continued)

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<tr>
<td>Comparing Patient Centered Outcomes in the Management of Pain between Emergency Departments and Dedicated Acute Care Facilities for Adults with Sickle Cell Disease.</td>
<td>Johns Hopkins University</td>
<td>Sophie Lanzkron</td>
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<td>Delivering Patient-Centered Adolescent Preventive Care with Training and Technology</td>
<td>Seattle Children's Hospital</td>
<td>Carolyn McCarty</td>
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<td>Describing the Comparative Effectiveness of Colorectal Cancer Screening Tests: The Impact of Quantitative Information</td>
<td>Indiana University</td>
<td>Peter Schwartz</td>
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<td>Development of a Patient-Directed Queries Network to engage Patients and Prioritize their Questions to inform the PCORI Research Agenda</td>
<td>University of Oklahoma Health Sciences Center</td>
<td>Zsolt Nagykaldi</td>
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<td>Development of the PROMIS Pediatric Sleep Health Item Banks</td>
<td>The Children's Hospital of Philadelphia</td>
<td>Christopher Forrest</td>
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<td>Engaging Stakeholders in Building Patient-centered, N-of-1 Randomized and Other Controlled Trial Methods</td>
<td>Columbia University Medical Center</td>
<td>Karina Davidson</td>
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<td>Estimation of Multi-Treatment Effects from Observational Data with Application to Diabetes Mellitus</td>
<td>Brown University</td>
<td>Roee Gutman</td>
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<td>Expanding PRO Assessment Integrated into Routine Clinical Care of Patients with HIV to New PROMIS Domains: Identifying Patient Priorities, Developing Cross-Walks with Legacy Instruments, and Evaluating Predictive Validity</td>
<td>University of Washington</td>
<td>Heidi Crane</td>
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<td>Expanding PROMIS Item Bank Development to the Pregnant Population</td>
<td>Cedars Sinai Medical Center</td>
<td>Kimberly Gregory</td>
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<td>Extending PROMIS Pain Item Banks: Pain Self-efficacy and Pain Catastrophizing</td>
<td>University of Washington</td>
<td>Dagmar Amtmann</td>
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<td>Feasibility of Implementing Patient-Reported Outcome Measures</td>
<td>National Committee for Quality Assurance</td>
<td>Sarah Scholle</td>
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<td>Improving Communication Between Cancer Patients and Oncologists Using Patient Feedback on Actual Conversations and the ABIM Maintenance of Certification Program.</td>
<td>Duke University</td>
<td>James Tulsky</td>
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<td>Improving Specialty-Care Delivery in Chronic Skin Diseases</td>
<td>University of Colorado Denver</td>
<td>April Armstrong</td>
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<td>Incorporating PROMIS Symptom Measures into Primary Care Practice</td>
<td>Indiana University</td>
<td>Kurt Kroenke</td>
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<td>The Louisiana Trial to Reduce Obesity in Primary Care</td>
<td>Pennington Biomedical Research Center</td>
<td>Peter Katzmarzyk</td>
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<td>Making PROMIS Meaningful to Patients and Providers in Clinical Practice</td>
<td>Johns Hopkins University</td>
<td>Clifton Bingham</td>
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<td>Measuring the Context of Healing: Using PROMIS in Chronic Pain Treatment</td>
<td>University of Pittsburgh</td>
<td>Carol Greco</td>
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<td>Methods for Heterogeneity of Treatment Effects: Random Forest Counterfactual Machines</td>
<td>University of Miami School of Medicine</td>
<td>Daniel Feaster</td>
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<td>Midwestern Collaborative for Treating Obesity in Rural Primary Care</td>
<td>University of Kansas Medical Center Research</td>
<td>Christie Befort</td>
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<td>North Carolina Prostate cancer Comparative Effectiveness &amp; Survivorship Study (NC ProCESS): A Stakeholder-Driven, Population-Based Prospective Cohort Study</td>
<td>University of North Carolina at Chapel Hill</td>
<td>Ronald Chen</td>
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<td>Optimization of Home Oxygen Weaning in Premature Infants</td>
<td>Children's Hospital Boston</td>
<td>Lawrence Rhein</td>
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<td>Patient-Centered Approaches to Research Enrollment Decisions in Acute Cardiovascular Disease</td>
<td>Emory University</td>
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<td>Patient-Centered CER of Home-Based Interventions to Prevent CA-MRSA Infection Recurrence</td>
<td>Clinical Directors Network, Inc.</td>
<td>Jonathan Tobin</td>
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<td>Patient-Centered Physical Activity Coaching to Improve Outcomes in COPD: A Pragmatic Trial</td>
<td>Kaiser Foundation Research Institute</td>
<td>Huong Nguyen</td>
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<td>Peer Support After NICU Discharge: Can Parent Navigation Improve Parental Mental Health and Infant Outcomes?</td>
<td>Children's National Medical Center</td>
<td>Karen Fratantoni</td>
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Spring 2014 Cycle Contracts (continued)

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<tr>
<td>Preventive Sexual Health Screening among Female-to-Male (FTM) Transgender Adult Patients</td>
<td>Fenway Community Health Center</td>
<td>Sari Reisner</td>
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<td>Programa Esperanza (Project Hope)</td>
<td>University of Southern California</td>
<td>Maria Aranda</td>
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<td>Project ACHIEVE (Achieving Patient-Centered Care and Optimized Health In Care Transitions by Evaluating the Value of Evidence)</td>
<td>University of Kentucky</td>
<td>Mark Williams</td>
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<td>Propensity Score-Based Methods for CER Using Multilevel Data: What Works Best When</td>
<td>Cincinnati Children’s Hospital Medical Center</td>
<td>Mi-Ok Kim</td>
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<td>Randomized Comparison of Evidence-Based Protocols for Adolescents with ADHD in Specialty Care: Behavioral Only versus Integrated Behavioral and Medication Interventions</td>
<td>National Center on Addiction/Substance Abuse</td>
<td>Aaron Hogue</td>
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<td>Stopping Anti-Tumor Necrosis Factor Agents in Rheumatoid Arthritis (STARA) Clinical Trial</td>
<td>Georgetown University</td>
<td>Arthur Weinstein</td>
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<td>Technology-Assisted Qualitative Research: How Does Modality Affect Outcome?</td>
<td>Family Health International</td>
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<td>The Comparative Effectiveness of Patient- and Provider-Directed Strategies for Increasing Shared Decision-Making in Reproductive Health Care</td>
<td>Dartmouth College</td>
<td>Rachel Thompson</td>
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<td>Using Question Prompt Lists During Pediatric Asthma Visits to Increase Adolescent Involvement</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Betsy Sleath</td>
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In addition to research contracts, PCORI approved a number of programmatic and research support awards in FY 2014. More information on these awards may be found at [www.pcori.org](http://www.pcori.org).
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 decisions 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. Disclosures reflect those reported to PCORI as of January 19, 2015.

Board of Governors

Debra J. Barksdale, PhD, RN
As of January 12, 2015
Financial Associations
• University of North Carolina at Chapel Hill - Employer
• Robert Wood Johnson Foundation Executive Nurse Fellow Program (Ended 10/31/14)
• American Psychiatric Nurses Association Preconference - Speaker
• Academic Center for Evidence-Based Practice, UT Health Science Center at San Antonio, Texas. - Speaker
• Frontier Nursing University - Speaker
• University of Colorado, Aurora, Colorado - Speaker
• National Black Nurses Association Day on Capitol Hill - Speaker
• Bon Secours Advanced Practice Nurses Conference - Speaker
• University of Pittsburgh - Visiting Professor

Personal Associations
• National Organization of Nurse Practitioner Faculties - Member and Past President
• American Association of Nursing - Member
• National League for Nursing – Member
• North Carolina Nurses Association – Member
• American Academy of Nursing – Member

Kerry Barnett, JD
As of November 24, 2014
Financial Associations
• Cambia Health Solutions (includes BlueCross/ BlueShield and other Affiliated Health Plans) – Employer
• Cambia Health Solutions and Affiliates – Officer and Corporate Secretary
• Gastroenterologist, partner in private group medical practice with ownership in ambulatory endoscopy center – Sibling Employer

Personal Associations
None reported

Lawrence Becker
As of November 8, 2014
Financial Associations
• Xerox Corporation – Employer
• Stock ownership:
  - Aetna, Inc.
  - GE
  - Johnson & Johnson, Inc.
  - Amgen
  - Pfizer, Inc.
  - SPDR Biotech
  - The Travelers Companies, Inc.
  - Ventas
  - GlaxoSmithKline
  - Bristol-Myers Squibb
  - LSB Consultants, LLC – company owned by wife

The University of Rochester Medical Center – Sibling employer

Personal Associations
• ERISA Industry Council – Board member
• The National Quality Forum – Board member
• Rochester Regional Health Information Organization – Board member
• Jewish Senior Life – Board member

Francis S. Collins, MD, PhD
As of January 15, 2015
Financial Associations
• National Institutes of Health, Director – Employer

Personal Associations
• Institute of Medicine – Member
• National Academy of Sciences – Member

Allen Douma, MD
As of December 11, 2014
Financial Associations
None reported

Personal Associations
• Jefferson Regional Health Alliance – Board member

Alicia Fernandez, MD
As of January 7, 2015
Financial Associations
• University of California, San Francisco – Employer
• Stock ownership:
  - Prosetta Bioconformatics

Personal Associations
• Society of General Internal Medicine – Member, Active Volunteer, Former Council member
• National Hispanic Medical Association – Member
• Institute of Medicine Roundtable on Literacy – Member

Christine Goertz, DC, PhD
As of November 11, 2014
Financial Associations
• Palmer College of Chiropractic – Employer
• American Chiropractic Association – Consultant
• Healthwise – Consultant
• Quality Insights of Pennsylvania – Consultant
• RAND Corporation – Consultant
• Prezacor, Inc. – Stock options

Personal Associations
• American Chiropractic Association – Member
• American Medical Association, Measures Implementation and Informatics Performance Improvement 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
• Global Spine Care Initiative - Member

Leah Hole-Marshall, JD
As of January 9, 2015
Financial Associations
• National Alliance for Caregiving, CEO – Employer
• International Alliance of Caregiving Organization, Secretariat – Member

Personal Associations
• Long Term Quality Alliance – Secretary of the Board of Directors
• Center for Aging Services Technology – Commissioner
• American Society on Aging – Member
• National Council on Aging – Member
• ReACT – Member
• Community Health Accreditation Program, Standards Quality Board – Member
• Gerontological Society of America – Member
• Partnership to Fight Chronic Disease – Member
• Institute for the Ages – Board Member
• C-TAC – Member
• National Complex Care Advisory Board (United Healthcare) – Board Member
• International Alliance of Patient Organizations – Member
• International Federation on Aging – Member

Gail Gibson Hunt
As of December 19, 2014
Financial Associations
• National Alliance for Caregiving, CEO – Employer
• International Alliance of Caregiving Organization, Secretariat – Member

Personal Associations
• Long Term Quality Alliance – Secretary of the Board of Directors
• Center for Aging Services Technology – Commissioner
• American Society on Aging – Member
• National Council on Aging – Member
• ReACT – Member
• Community Health Accreditation Program, Standards Quality Board – Member
• Gerontological Society of America – Member
• Partnership to Fight Chronic Disease – Member
• Institute for the Ages – Board Member
• C-TAC – Member
• National Complex Care Advisory Board (United Healthcare) – Board Member
• International Alliance of Patient Organizations – Member
• International Federation on Aging – Member

Robert Jesse, MD, PhD
As of January 5, 2015
Financial Associations
• Department of Veterans Affairs/Veterans Health Admin. Chief Officer, Academic Affiliations - Employer
• Virginia Commonwealth University Health System – Faculty
• Veracis, Inc. – Spouse, Consulting Fees

Personal Associations
• American Heart Association – Fellow
• American College of Cardiology – Fellow
• Society of Cardiovascular Patient Care – Board
• Richmond Metro Chapter of the American Heart Association – Board
• American Board of Internal Medicine – Diplomate
Richard E. Kronick, PhD  
As of January 15, 2015  
Financial Associations  
• Agency for Healthcare Research & Quality (AHRQ), Director – Employer  
Personal Associations  
• National Quality Forum – Board member  
• University of California, San Diego – Faculty (unpaid leave of absence)  

Harlan M. Krumholz, MD, SM  
As of January 15, 2015  
Financial Associations  
• Yale University, Professor of Medicine – Employer  
• United Healthcare, Cardiac Scientific Advisory Board – Chair  
• ImageCOR, LLC – Founder  
• American Heart Association – Editor  
• Medtronic, Inc. – Principal Investigator on research agreement through Yale University  
• Johnson & Johnson (Janssen) – Principal Investigator on research agreement through Yale University  
• Premier, Inc. – Consultant  
• Fujifilm Hospital – Consultant  
• Element Science, Inc. – Consultant  

Richard E. Kuntz, MD, MSc  
As of November 11, 2014  
Financial Associations  
• Medtronic, Inc. – Employer  
• Tengion – Board Member (receives fee as Director)  

Personal Associations  
• Minnesota Medical Foundation  
• Case Western Reserve Medical School – Board of Visitors  
• Chiari & Syringomyelia Foundation  

Sharon Levine, MD  
As of December 15, 2014  
Financial Associations  
• Agency for Healthcare Research & Quality (AHRQ), Director – Employer  

Personal Associations  
• National Quality Forum – Board member  
• University of California, San Diego – Faculty  

Freda Lewis-Hall, MD  
As of December 8, 2014  
Financial Associations  
• Pfizer, Inc. – Employer  
• Tenet Health – Board of Directors  
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  
- Bristol-Myers Squibb  
- Vertex Pharmaceuticals Inc.  

Pension Plans:  
- Bristol-Myers Squibb Savings Plan  
- Bristol-Myers Squibb 401(k) Profit Sharing Plan  
- Lilly Pension Retirement Plan  
- Vertex 401k Plan  
- Howard University Retirement Plan  

Personal Associations  
• 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 (STO) – Board member  
• NCCATS Advisory Council – Council member  
• NCAT/Cures Acceleration Network Review (CAN) – Chair  
• Clinical Trials Transformation Initiative – Executive Committee  

Steven Lipstein, MHA (Vice Chairperson)  
As of November 11, 2014  
Financial Associations  
• BJC HealthCare, President and CEO – Employer  

Personal Associations  
• Emory University – Trustee  
• Washington University in St. Louis – Trustee  
• Missouri Hospital Association – Trustee  
• Boston Children’s Hospital – Relative is an employee  
• St. Louis Regional Health Commission – Commissioner  
• Institute of Medicine – Member  

Barbara J. McNeil, MD, PhD  
As of November 21, 2014  
Financial Associations  
• Brigham & Women Hospital – Employer  
• Harvard University Medical School – Employer  
• Edwards Lifesciences Corp – Investments, Consulting Fee, Board Member  
• Marine Polymer Technologies – Consulting Fees, Medical Advisor  
• BNY Mellon Professionally Managed Investment Account (Diversified)  

Personal Associations  
• AgMednet, Inc. – Board of Directors  
• Boston Foundation for Sight – Board of Directors  
• Institute of Medicine – Member  
• American Academy of Arts & Sciences  
• Food & Drug Administration Advisory Committee to Review Status of FDA  
• Blue Cross, Blue Shield Medical Advisory Committee  

Ellen V. Sigal, PhD  
As of December 9, 2014  
Financial Associations  
• Baxter Financial – Common Stock IRA  

Personal Associations  
• American Psychiatric Association (APA) – Fellow  
• APA Council on Quality – Member  
• American Psychiatric Foundation (Component of APA) – Board of Directors  
• Academy Health – Fellow  
• Mississippi Psychiatric Association – Member of Executive Board  
• Emory University School of Medicine, Department of Psychiatry  

Grayson Norquist, MD, MSPH (Chairperson)  
As of November 26, 2014  
Financial Associations  
• University of Mississippi Medical School – Employer  

Personal Associations  
• American Psychiatric Association (APA) – Fellow  
• APA Council on Quality – Member  
• American Psychiatric Foundation (Component of APA) – Board of Directors  
• Academy Health – Fellow  
• Mississippi Psychiatric Association – Member of Executive Board  
• Emory University School of Medicine, Department of Psychiatry  

Ellen V. Sigal, PhD  
As of December 9, 2014  
Financial Associations  
• Baxter Financial – Common Stock IRA  

Personal Associations  
• American Psychiatric Association (APA) – Fellow  
• APA Council on Quality – Member  
• American Psychiatric Foundation (Component of APA) – Board of Directors  
• Academy Health – Fellow  
• Mississippi Psychiatric Association – Member of Executive Board  
• Emory University School of Medicine, Department of Psychiatry  

Harlan F. Weisman, MD  
As of December 1, 2014  
Financial Associations  
• And-One consulting, LLC – Managing Director and paid Consultant  
• ControlRad, Inc. – Board Director, Stock and Stock Options  
• BioMotic LLC - Scientific Advisory Board member (Compensation)  
• Johnson & Johnson – Pension, stock and Stock Options  
• Coronoado Biosciences, Inc. – Stock and Stock Options  
• Mendham Investment Group, LLC – Member  
• Huchison Biofilm Medical Solutions – Board of Directors and Advisor (Compensation and restricted stock)  

Personal Associations  
• American Heart Association – Fellow  
• American College of Cardiology – Fellow  
• American College of Chest Physicians – Fellow  
• American Medical Association  
• American Association for the Advancement of Science  
• American Association for Medical Research
Robert Zwolak, MD, PhD
As of January 19, 2015

Financial Associations
- Dartmouth-Hitchcock Clinic – Employer
- US Department of Veterans Affairs – Employer
- Society for Vascular Surgery – Consultant
- Various Academic Centers – Honoraria for Visiting Professorships
- Eva Corporation (medical device manufacturer) – Investments

Personal Associations
- Intersocietal Commission for Accreditation of Carotid Stent Facilities – Board of Directors
- AMA/Specialty Society Relative Unit Update Committee – Member of Work Groups
- Society for Vascular Surgery – Health Policy Consultant, Past President
- American College of Surgeons – Member of Committees and Work Groups
- New England Society for Vascular Surgery – Member
- American Venous Forum – Member
- Society for Vascular Ultrasound – Member
- Geisel School of Medicine at Dartmouth – Professor (unpaid position)
- Eastern Vascular Society – Member

Methodology Committee
Naomi Aronson, PhD
As of November 6, 2014

Financial Associations
- Blue Cross Blue Shield Association, Technology Evaluation Center – Employer
- Agency for Health Research and Quality – Under contract

Personal Associations
- Pew Charitable Trust, Medical Device Registry Project – Technical Advisor
- Health Technology Assessment International Health Policy Forum
- Institute of Medicine Genomics Roundtable
- National Business Group on Health Committee on Evidence-Based Benefit Design
- University of Toronto’s Internal Canada Foundation for Innovation – External Reviewer in 2012
- Center for Medical Technology Policy, Green Park Collaborative USA: Oncology Consortium; Metabolic Diseases Consortium
- Sustainable Predictive Oncology Therapeutics and Diagnostics (SPO/T/Dx) Working Group, Tapestry Networks
- Society to Improve Diagnosis in Medicine (Pertinent Previous: IOM Forum on Drug Discovery Translation and Development 2005-2006)
- American Gastroenterological Association Institute, Tech Summit – Faculty

Ethan Basch, MD, MSc
As of January 14, 2015

Financial Associations
- University of North Carolina, Chapel Hill – Employer
- Memorial Sloan-Kettering Cancer Center – Employer

Personal Associations
- National Cancer Institute – Board of Scientific Advisors
- Journal of the American Medical Association – Associate Editor
- Alliance for Clinical Trials in Oncology – Chair
- American Society of Clinical Oncology – Task Force Chair

David R. Flum, MD, MPH
As of January 15, 2015

Financial Associations
- University of Washington, Department of Surgery – Employer
- Benchmark Medical, LLC – Partial Ownership
- Agency for Healthcare Research & Quality, US DHHS (contracts), Consumers Union (Consultant)
- Lectures at several universities in the US and abroad

Personal Associations
- Academy Health – Member, Committee member
- American College of Physicians – Member
- Society for General Internal Medicine – Member
- Society for Medical Decision Making – Member, Committee member
- U.S. Cochrane Center – Advisory Board

Cynthia J. Girman, DrPH
As of January 8, 2015

Financial Associations
- Merck & Co., Inc. – Retired employee as of 12/31/2014
- Merck & Co., Inc. – Stock ownership (self and spouse)
- CERobs Consulting, LLC – President and Consultant

Personal Associations
- Department of Epidemiology, University of North Carolina – Adjunct Associate Professor (unpaid position)
- Center for Pharmacoeconomics, UNC, Scientific Advisory Board – Member (unpaid position)
- International Society of Pharmacoeconomics – Member
- ISPE CER Special Interest Group, ICPE Education Committee – Member
- International Society for Pharmacoconomics and Outcomes Research – Member
- Drug Information Association – Member
- Drug Information Association CER Scientific working group – Member

Steve Goodman, MD, MHS, PhD
(Vice Chairperson)
As of January 14, 2015

Financial Associations
- Stanford University – Employer
- National Blue Cross-Blue Shield Technology Evaluation center – Member, Medical Advisory Panel
- American College of Physicians, Annals of Internal Medicine – Statistical Editor
- Hoffmann LaRoche – Legal Consulting

Personal Associations
- Society for Clinical Trials – Member
- American College of Epidemiology – Member

Mark Helfand, MD, MS, MPH
As of January 14, 2015

Financial Associations
- Portland VA Medical Center, Portland, OR (Hospital and Clinics) – Employer
- Oregon Health and Science University, Portland, OR (Hospital and Clinics) – Employer
- Geragos & Geragos, Los Angeles, CA – Expert Witness

Personal Associations
- Society for Medical Decision-Making – President-elect
- U.S. Cochrane Center, West Coast Branch – Director
- Academy Health, Methods Council – Member
- American College of Physicians – Member
- Research Grants, Contracts, Consulting, Teaching:
  - U.S. Department of Veterans Affairs (grants)
  - Agency for Healthcare Research & Quality, US DHHS (contracts)
  - Lectures at several universities in the US and abroad

Robert M. Kaplan, PhD
As of November 6, 2014

Financial Associations
- Agency for Healthcare Research and Quality – Employer
- Proctor & Gamble – Stock
- Stryker Corporation – Stock

Personal Associations
- University of California, San Diego – Faculty (unpaid position)
- University of California, Los Angeles – Distinguished Professor Emeritus, Retired
- National Institutes of Health, Office of the Director – Former Employer
- University of Tennessee Health Science Center, Assistant Professor of Preventative Medicine – Son
- University of Tennessee Health Science Center, Assistant Professor of Preventative Medicine – Daughter-in-law

Michael S. Lauer, MD
As of January 21, 2015

Financial Associations
- National Institutes of Health – Employer
- Savings Investment Plan
- Putnam College Fund
- UptoDate Inc.

Personal Associations
None reported

David O. Meltzer, MD, PhD
As of January 12, 2015

Financial Associations
- University of Chicago – Employer
- CVS
- National Institutes of Health
- American Board of Internal Medicine
- Grants:
  - CMMI
  - NIH
  - AHRQ
  - PCORI
  - Richmond Foundation
  - Robert Woods Johnson Foundation (RWJF)
  - National Pharmaceutical Foundation
Personal Associations
• American Board of Internal Medicine – Member
• Society of General Internal Medicine - Member
• Society for Medical Decision Making – Member
• University of Chicago

Brian S. Mittman, PhD
As of January 15, 2015

Financial Associations
• US Department of Veterans Affairs – Employer
• Kaiser Permanente Southern California – Employer
• Sepulveda Research Corp., VA Nonprofit Research Foundation – Employer
• UCLA School of Medicine – Consultant
• Dana Farber Cancer Institute – Consultant
• RAND Corporation – Consultant
• Washington University in St. Louis – Consultant
• Westat – Consultant
• University of Maryland Baltimore – Consultant

Personal Associations
• AcademyHealth – Member, Methods Council, Education Council; Member, Advisory Group, Delivery System Science Fellowship Program
• Association of American Medical Colleges – Member, Advisory Panel on Research
• Kings College London Centre for Implementation Science/CLAHRSC South London – Member, External Advisory Board
• Canadian Partnership Against Cancer, Knowledge Management Steering Committee – Member
• Mayo Clinic Center for Clinical and Translational Science – Consultant

Sally C. Morton, PhD
As of November 9, 2014

Financial Associations
• University of Pittsburgh – Employer
• RAND Corporation – Consultant, AHRQ Contract
• RTI International – Consultant, AHRQ Contract
Contracts/Grants from:
- AHRQ
- National Institutes of Health
- National Pharmaceutical Council
- PCORI

Personal Associations
• AHRQ – Committee Member
• American Assn for the Advancement of Science – Past Chair, Section U (Statistics)
• American Statistical Association – Committee Member
• Caucus for Women in Statistics – Member
• Institute of Mathematical Statistics – Member
• Society for Research Synthesis Methodology – Elected Member

Robin Newhouse, PhD, RN (Chairperson)
As of November 22, 2014

Financial Associations
University of Maryland, School of Nursing, Chair, Organizational Systems and Adult Health – Employer

Personal Associations
• Speaker Honorarium:
  - Midwest Nursing Research Society
  - Southern Nursing Research Society
  - University of Arkansas
  - University of Michigan
  - University of Minnesota
  - Cincinnati Children’s Hospital Medical Center
• VHA, Inc. – Consultation
• Worldviews on Evidence-Based Nursing – Associate Editor
• Get Well Network, O’Neil Clinical Advisory Council
• RWJ Nurse Faculty Scholar Mentor
• Righttime Medical Care – Child Employer
• AHRQ Research Funding Awards – Serving as PI or Co-Investigator on various projects
• PhRMA Foundation Grant Funding – Serving as Co-Investigator on project

Personal Associations
• American Nurses Credential Center – Research Council Chair
• AcademyHealth (Board of Directors)
• Institute of Medicine (Committee Member)
• Institute of Medicine Committee on Treatment of Cardiac Arrest, 2014-15
• Planning Committee, Future Directions of Credentialing Research in Nursing: A Workshop, 2014
• Institute of Medicine Standing Committee on Credentialing Research in Nursing, 2012-14
• American Academy of Nursing – Member
• Council for the Advancement of Nursing Science – Member
• Sigma Theta Tau International Honor Society of Nursing – Member
• Southern Nursing Research Society – Member
• American Organization of Nurse Executives – Member
• Council for Graduate Education for Administration in Nursing – Member

Neil R. Powe, MD, MPH, MBA
As of December 12, 2014

Financial Associations
• University of California, San Francisco – Employer
• National Institutes of Health, Research Grants
• Centers for Disease Control and Prevention, Research Grants
• Robert Wood Johnson Foundation, National Advisory Committees
• American Board of Internal Medicine, Practice Improvement Committee
• Informed Medical Decisions Foundation/Healthwise – Medical Editor
• Parkland Center for Clinical Innovation – Board Member
• Vanderbilt University School of Medicine, Scientific Advisory Board

Personal Associations
Professional Societies/Association Membership:
- Institute of Medicine (IOM)
- American Society for Clinical Investigation (ASCI)
- AAP
- APM
- Society of General Internal Medicine
- American College of Physicians

- American Society of Nephrology
- Academy Health
- American Public Health Association
- AES
- ACCA
- American Society of Nephrology, Quality Metrics Task Force

Sebastian Schneeweiss, MD, ScD
As of January 15, 2015

Financial Associations
• Brigham and Women’s Hospital – Employer
• Harvard School of Public Health – Teaching
• Harvard Medical School – Teaching
• WHISCON, LLC – Consulting
• Neblett, Beard & Arsenault – Consultant
• Aetion, Inc. – Consultant and Equity Holder

Personal Associations
• International Society for Pharmacoepidemiology – Member and Fellow
• International Society for Pharmacoepidemics and Outcomes Research – Member
• American Society for Clinical Pharmacology and Therapeutics – Member
• American College of Epidemiology – Fellow
• American College of Clinical Pharmacology – Fellow

Mary Tinetti, MD
As of December 11, 2014

Financial Associations
• Yale University – Employer
• National Institutes of Health – Funding Source
• Hartford Foundation – Funding Source
• Journal of the American Medical Association (JAMA) – Viewpoint Editor
• MacArthur Foundation – Funding

Personal Associations
Assn of Directors of Geriatric Academic Programs (ADGAP) – Board of Directors

Clyde W. Yancy, MD, MSc
As of January 15, 2015

Financial Associations
• National Institutes of Health – Special Government Employee
• Medscape/theheart.org – Consultant

Personal Associations
• American Heart Association – Board Member, Chicago Metro Board; Past National President (2009-2010)
• American College of Cardiology – Committee Member
• American College of Physicians – Member
• Association of Black Cardiologists – Member, Educator
• American Hospital Association – Committee Member, Health Equity
• Heart Failure Society of America – Committee member
• Heart Rhythm Society - Member

A-11
PCORI Executive Staff
Note: COI disclosures for all PCORI staff are available at www.pcori.org/people

Joe V. Selby, MD, MPH
As of August 6, 2014
Financial Associations:
• University of California, San Francisco, Employer (Child)
Personal Associations:
• None reported

Bryan Luce, PhD, MS, MBA
As of August 18, 2014
Financial Associations:
• None reported
Personal Associations:
• Medical Device Innovation Consortium, Board Member

Jean R. Slutsky, PA, MSPH
As of July 15, 2014
Financial Associations:
• None reported
Personal Associations:
• AcademyHealth Methodology Council, Member

Regina L. Yan, MA
As of July 16, 2014
Financial Associations:
• None reported
Personal Associations:
• None reported

Mary C. Hennessey, Esq.
As of July 15, 2014
Financial Associations:
• None reported
Personal Associations:
• Health and Human Services Advisory Council on Blood Stem Cell Transplantation, Member

PCORI Advisory Panels
Names of the members of PCORI's Advisory Panels and their Conflict of Interest disclosure statements are available at www.pcori.org/advisory-panels
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Independent Auditor’s Report

To the Audit and Conflict of Interest Sub-Committee of the Governance Committee of the Board of Governors
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 September 30, 2014 and 2013, the related statements of activities, cash flows and functional expenses for 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 September 30, 2014 and 2013, 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 Matter
Our audits were conducted for the purpose of forming an opinion on the financial statements as a whole. The Management’s Discussion and Analysis, on pages 3 – 9, is presented for purposes of additional analysis and is not required part of the basic financial statements. Such information has not been subjected to the auditing procedures applied in the audit of the basic financial statements, and accordingly, we do not express an opinion or provide any assurance on it.

Other Reporting Required by Government Auditing Standards
In accordance with Government Auditing Standards, we have also issued our reports dated March 3, 2015 and March 10, 2014, 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 those reports 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. Those reports are an integral part of an audit performed in accordance with Government Auditing Standards in considering PCORI’s internal control over financial reporting and compliance.

Gaithersburg, Maryland
March 3, 2015
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized in 2010 by the Patient Protection and Affordable Care Act (42 U.S.C. 1301 et seq.) (Act) 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.” It does this by supporting comparative clinical effectiveness research (CER) projects designed to answer questions most important to patients. PCORI is also 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)(1) nonprofit corporation, governed by a 21-member multi-stakeholder Board of Governors, including 19 members appointed by the Comptroller General of the United States. 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). The Act also provides that the Directors of the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), or their designees, be members of the Board.

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 CER. 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, CER, biostatistics, genomics, and research methodologies. In September 2014, three new committee members were appointed: Cynthia Girman, DrPh, Sally Morton, PhD, and Neil R. Powe, MD, MPH, MBA. They replaced three of four departing committee members: Sherine Gabriel, MD, MSc, Sharon-Lise Normand, PhD, Alfred Berg, MD, MPH, and John Ioannidis, MD, DSc. At the end of the fiscal year, a fourth replacement was pending.

PCORI’s Board is guided by five committees with specific areas of focus—Engagement, Dissemination, and Implementation; Research Transformation; Science Oversight; Finance and Administration; and Governance. The Governance Committee is comprised of two subcommittees: Audit and Conflict of Interest and Executive Evaluation and Compensation. In February 2014, Alicia Fernandez, MD was appointed to the Board to fill the seat made vacant when former Board Chair, Eugene Washington, MD, MS stepped down at the end of his term. Barbara J. McNeil, MD, PhD was appointed to the Board on September 30, 2014. Dr. McNeil was selected to replace outgoing Board member Arnold Epstein, MD who became ineligible to continue on the Board after joining the U.S. Department of Health and Human Services as the new Deputy Assistant Secretary and head of the Office of Health Policy in the Office of the Assistant Secretary for Planning and Evaluation.

Important Financial Reporting Update

In calendar year 2013, the Board of Governors voted to change the financial reporting period for the corporation to a fiscal year that begins on October 1 and ends on September 30 of each year. The audited financial statements for the calendar year 2012 and the nine-month fiscal year January 1, through September 30, 2013, were presented for illustration purposes only in the audit report dated March 10, 2014. During FY 2014, management engaged an independent audit of the financial records at September 30, 2012 so that the beginning balances for FY 2013, October 1, 2012, could be substantiated and the comparative financial statements for FY 2013 and FY 2014 could be presented herein.
CURRENT ACTIVITIES

Driving PCORI’s Mission

In November 2013, the Board of Governors approved PCORI’s strategic plan as an overall framework for all of PCORI’s activities. The plan focuses on funding and conducting highly relevant research that is likely to change practice and improve patient outcomes; on disseminating and promoting the implementation of the results of this research; and on influencing how clinical research is done by others, so that a greater proportion of all clinical research is useful to patients and other healthcare decision makers. The strategic framework that underlies the plan has three 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 (PCOR) evidence; and
- Influence clinical and healthcare research funded by others to be more patient-centered.

To reach these goals, PCORI organized its work at both the staff and governance levels into five mutually reinforcing strategic imperatives: Engagement, Methods, Research, Dissemination, and Infrastructure.

Engagement

PCORI’s engagement strategies include developing a skilled community of patients, caregivers, and stakeholders from across the entire healthcare enterprise and involving them meaningfully in every aspect of research. These strategies serve PCORI’s goals by seeking to increase the usefulness and trustworthiness of the information produced, facilitating its dissemination and uptake, and exposing more researchers and other stakeholders to the model of patient-centered research. Engagement is intended to increase the chances that the right research questions are asked, that the design and conduct of the research we fund provides information needed by the end-users, and that study findings are interpreted appropriately and communicated effectively.

FY 2014 was a year in which PCORI solidified its Engagement activities as a path to rigorous, patient-centered comparative clinical effectiveness research through a number of ongoing and new initiatives.

PCORI introduced the Engagement Rubric (originally called the Patient and Family Engagement Rubric), in the Winter 2014 cycle to provide guidance to researchers on how to meaningfully engage patients and other stakeholders throughout the entire research process including dissemination and implementation of relevant evidence. To operationalize the Engagement Rubric, the role of the Engagement Officer was initiated in March. New to the world of patient-centered healthcare and research, this role is a bridge between PCORI’s Science and Engagement program staff. The Engagement Officer role is woven through the research continuum helping to determine engagement milestones and monitor the engagement activity during the research including the development of plans for dissemination of study findings. Engagement applied from a study’s start to finish not only advances relevant science but also helps speed the progression of findings into practice.

Further strengthening the bridge between Science and Engagement, funding mechanisms were also created to offer partnership development, capacity building, and training opportunities to ensure successful participation of all stakeholders in PCOR.
The Pipeline to Proposal Award Program, introduced in 2014, is a tiered, micro contract funding initiative to facilitate the submission of high-quality research proposals by providing support for partnership development and capacity building of PCOR partners. In addition to the Pipeline to Proposal Award Program, the Eugene Washington Engagement Awards Program provides a platform to expand the role of all stakeholders in research. It encourages active integration of patients, caregivers, clinicians, and other healthcare stakeholders as integral members of the research process. During the fiscal year, PCORI accepted applications and funded awards in the following categories:

- **Knowledge Awards:** These projects build knowledge about how consumers of healthcare information view patient-centered outcomes research and comparative effectiveness research, how they make use of PCOR/CER findings, and what evidence they need to reach health and healthcare decisions.

- **Training and Development Awards:** These projects build capacity for healthcare community engagement in PCOR/CER by funding awards that promote training, the creation of methods to connect patients and other stakeholders with the research community, and facilitate engagement in PCOR/CER.

- **Dissemination Awards:** These projects support activities that develop channels for dissemination and implementation of PCOR/CER evidence.

The PCORI Ambassador Program was also formalized in 2014. The initiative will equip, train and mobilize patients, organizations, and other stakeholders to share PCORI’s vision, mission, and PCOR principles with their respective communities, participate as full partners in research, and to help assure the sharing and uptake of information generated from PCORI-funded projects.

PCORI engagement strategies include developing a skilled community of patients and other stakeholders from across the entire healthcare enterprise and involving them meaningfully in every aspect of our work—from the development of our research priorities to the dissemination of research findings. These strategies aim to increase the usefulness and trustworthiness of the information we produce, facilitating its dissemination and uptake.

**Building on PCORI’s Methodology Standards**

Good methods are essential to producing high-quality PCOR and the PCORI Methodology Committee has developed guidelines for PCORI and for the broad community of researchers who conduct PCOR. The PCORI Methodology Standards were created to ensure that PCORI research is highly rigorous. The first component is a clinical prioritization process and research translation framework that helps make PCORI’s research agenda transparent and accessible to stakeholders. The second component is a set of standards that provide specific guidance for the design and conduct of individual PCOR projects. The PCORI Methodology Standards underwent extensive public review and revision based on public comment and in November 2013, PCORI released a substantially revised Methodology Report which put the previously released standards into broader context. With the release of the revised report, the Methodology Committee began work on a plan to broadly disseminate the report and the standards that all research programs must adhere to, the best practices in planning, design, and conduct of every individual research project funded by the institute, and oversight by program staff, monitoring project adherence to the standards.
Managing the Research Portfolio

PCORI awards funding for research through PCORI Funding Announcements (PFAs), broad calls for projects under the five National Priorities for Research and the Research Agenda as well as targeted announcements on specific high-priority topics and additional special funding opportunities. In FY 2014, PCORI’s Board of Governors approved 163 research awards totaling more than $348 million. There were three broad cycles and three targeted announcements funded in addition to the $94 million invested in Phase I funding for PCORnet, PCORI’s effort to develop a national patient-centered clinical research network. This large, highly representative electronic-data infrastructure is designed to improve the nation’s capacity to conduct CER and other types of outcomes studies through collaboration between health system-based and patient organization-based research networks. Including FY 2014 awards, PCORI has funded 360 research awards, $671 million in 39 states, from inception through September 30, 2014.

To see that the projects PCORI funds will have optimal impact and applicability in patient care, program staff exercises active and intensive portfolio planning, management, and evaluation of every aspect of the research agenda and mix of research projects across the organization including ensuring that PCORI funding is not duplicative of support that other funders might provide our awardees. The care taken in developing and managing the research portfolio is intended to improve the science of PCOR and the value of the information it produces.

One aspect of portfolio planning that is particularly relevant to influencing how research is conducted outside of PCORI is co-funding and the use of collaborative arrangements with federal agencies and other organizations that fund health research, such as the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH).

Additional Programmatic Activities Supported in Fiscal Year 2014

In addition to research funding, PCORI awarded a series of programmatic activities through contracts that were competed and evaluated using an RFP process. Those contracts included:

- Scientific Survey Services
- PCOR/CER Roadmap for State Policymakers
- National Patient-Centered Clinical Research Network Coordinating Center
- Comprehensive PCORI Training Curriculum Development Project
- Pipeline to Proposal Award Administration

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

- Comprehensive Website Redesign and E-mail Communications System
- Customer Relationship Management (CRM) System
- Grants/Contracts Management System

Building a Framework for Dissemination and Implementation

PCORI’s primary strategy for disseminating PCOR and supporting its use includes engaging patients and stakeholders in the research process from the very beginning; funding research to improve the effectiveness of communication and dissemination of research findings; and facilitating the usability, accessibility, and availability of information through best practices for the development of communication and dissemination materials and activities. In 2014, PCORI began developing a framework and toolkit for Dissemination and Implementation and engaging a broad range of stakeholders who helped shape the documents as well as provided input in how to most effectively see the results of the research funded by PCORI get to the audiences that need the information and in a format that is most useful to them. In the late summer and early fall of 2015, the pilot projects and the first round of PCORI funded primary research projects will be completed. Dissemination activities will follow on from the completed projects.
Beginning to Design a Framework for Peer Review

PCORI began developing a process for peer-reviewing primary research and making research findings publicly available in a form and format useful to patients, clinicians, and others during FY 2014. This process is part of PCORI’s broad dissemination and implementation plan to put knowledge gained from patient-centered outcomes research into practice. Input from patients and the entire health care community is a vital part of developing this process and in September 2014, PCORI launched a 54-day public comment period on PCORI’s draft Proposal for Peer Review of Primary Research and Public Release of Research Findings. The draft proposal outlines PCORI’s plan to conduct peer review of the primary research it funds and a process for making the findings publicly available.

Determining Success and Monitoring Progress

PCORI has set three goals; increasing information, speeding implementation, and influencing research. PCORI believes it will have succeeded in increasing information when it has produced a substantial body of usable answers to critical, patient-centered, comparative health questions. PCORI hopes to demonstrate that a substantial proportion of usable findings have been implemented within five years of publication; the benchmark for success in speeding implementation, and ultimately, when PCORI funding is complemented by increases in funding for PCOR from other sources, PCORI will have successfully demonstrated the ability to reach the needed magnitudes of scale to have influence over research.

In FY 2014, PCORI emphasized a commitment to work as a learning organization and it fully established the evaluation function. The PCORI Evaluation Group is a consultative task force that includes Board of Governors and Methodology Committee members as well as external experts. This group helped develop the Evaluation Framework and plans, review ongoing evaluation activities, analyze early results, and disseminate the evaluation work. The Board of Governors’ Dashboard and related materials, which are presented to and discussed with the Board of Governors in public, evolved substantially over the course of the year and now, in most instances, show progress against targets and over time.

PCORI also developed and launched Evaluation webpages, which organize, make accessible to the public, and seek feedback on all of the evaluation work. These webpages include materials from PCORI Evaluation Group meetings; our Evaluation Framework; Dashboard materials; results of our portfolio analyses, surveys, and other evaluation activities; and evaluation presentations and publications.

Financial Highlights

In fiscal year ended September 30, 2010, $1.26 billion was appropriated for the Patient-Centered Outcome Research Trust Fund (PCORTF): $10 million for fiscal year 2010, $50 million for fiscal year 2011, and $150 million a year for each of the eight years, 2012 through 2019. These amounts, less the annual 20% distribution to AHRQ and HHS beginning in 2011, are available to PCORI without further appropriation.

PCORI prepares annual financial statements in accordance with U.S. Generally Accepted Accounting Principles (GAAP), as issued by the Financial Accounting Standards Board (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.
The following table highlights key components of PCORI's financial statements during FY 2014:

<table>
<thead>
<tr>
<th>Financial Data</th>
<th>FY 2014</th>
<th>FY 2013</th>
<th>Increase/(Decrease)</th>
<th>Percentage Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of Financial Position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assets</td>
<td>$646,762,631</td>
<td>$345,432,368</td>
<td>$301,330,263</td>
<td>87%</td>
</tr>
<tr>
<td>Liabilities</td>
<td>45,109,150</td>
<td>7,806,399</td>
<td>37,302,751</td>
<td>478%</td>
</tr>
<tr>
<td>Net Assets</td>
<td>$601,653,481</td>
<td>$337,625,969</td>
<td>$264,027,512</td>
<td>78%</td>
</tr>
<tr>
<td>Statement of Activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue</td>
<td>$425,889,688</td>
<td>$240,837,570</td>
<td>$185,052,118</td>
<td>77%</td>
</tr>
<tr>
<td>Expenses</td>
<td>161,862,176</td>
<td>48,575,961</td>
<td>113,286,215</td>
<td>233%</td>
</tr>
<tr>
<td>Change in Net Assets</td>
<td>$264,027,512</td>
<td>$192,261,609</td>
<td>$71,765,903</td>
<td>37%</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 the 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 at September 30, 2014, were $601.7 million. Specifically, PCORI’s total assets of $646.8 million included $619.0 million of funds held in trust and $7.4 million in cash. Total liabilities of $45.1 million represent accounts payable, accrued expenses, and deferred rent.

**Statements of Activities:** In FY 2014, revenue and support totaled $425.9 million, of which $120 million came from appropriations, $85.6 million from the Federal Hospital Insurance (FHI) and Federal Supplementary Medical Insurance (FSMI) trust funds, $220.1 million from PCOR fees, and $0.2 million is from interest earned on the PCORTF investment portfolio.

**Please note:** For the fiscal year ending September 30, 2014, the revenue of $425.9 million include revenues in FY 2014 includes estimated PCOR fees actually deposited into the PCORTF on September 30, 2014 less an allowance for doubtful collection. Management is in possession of certain federal agency-generated estimates that could be used for estimating the total realizable fiscal year 2014 PCOR fee net revenue on an accrual basis; however, accounting standards dictate that estimates should be based on historical experience and other assumptions that are considered reasonable under given circumstances. Management is of the opinion that, given the complexity of the fee calculations, without historical perspective, estimates cannot be relied upon, so PCOR fee revenue will be taken into revenue as it is received less an allowance, at least until such a time as management believes that it has confidence in an estimating protocol.

Expense levels increased between FY 2014 and FY 2013. The increase from $48.6 million to $161.9 million is driven primarily by the growing research portfolio; $118.2 million was spent on extramural and internal research projects that have a life cycle ranging from three to five years. With the expansion of the research portfolio, there was an increase of $7.4 million in salaries, wages, and benefits resulting from the focus on building infrastructure and acquiring staff to manage the growing portfolio.
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, D.C. 20036, or Finance@pcori.org. Additional information regarding PCORI’s operations can be found at www.pcori.org.
## Patient-Centered Outcomes Research Institute

### Statements of Financial Position
September 30, 2014 and 2013

<table>
<thead>
<tr>
<th>Assets</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>$7,434,184</td>
<td>$25,063,381</td>
</tr>
<tr>
<td>Amounts Held by PCOR Trust Fund (Note 2)</td>
<td>619,000,553</td>
<td>286,660,865</td>
</tr>
<tr>
<td>Prepaid Expenses</td>
<td>13,058,189</td>
<td>29,794,339</td>
</tr>
<tr>
<td>Deposits and Other Assets</td>
<td>1,311,904</td>
<td>611,427</td>
</tr>
<tr>
<td>Property and Equipment, Net (Note 3)</td>
<td>5,957,801</td>
<td>3,302,356</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td><strong>646,762,631</strong></td>
<td><strong>345,432,368</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>$43,309,186</td>
<td>$6,658,910</td>
</tr>
<tr>
<td>Deferred rent and tenant improvement allowance</td>
<td>1,799,964</td>
<td>1,147,489</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td><strong>45,109,150</strong></td>
<td><strong>7,806,399</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commitments and Contingencies (Notes 4, 5, 6, 7 and 8)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Assets</td>
<td></td>
</tr>
<tr>
<td>Unrestricted</td>
<td>601,653,481</td>
</tr>
<tr>
<td><strong>Total Net Assets</strong></td>
<td><strong>646,762,631</strong></td>
</tr>
</tbody>
</table>

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

Statements of Activities
For the Years Ended September 30, 2014 and 2013

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue and Support (Note 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal appropriations</td>
<td>$ 120,000,000</td>
<td>$ 120,000,000</td>
</tr>
<tr>
<td>Patient-Centered Outcomes Research Fee</td>
<td>220,114,698</td>
<td>79,133,587</td>
</tr>
<tr>
<td>Transfers from the Federal Hospital Insurance (FHI) and the Federal Supplementary Medical Insurance (FSMI) trust funds</td>
<td>85,573,600</td>
<td>41,596,000</td>
</tr>
<tr>
<td>Interest income</td>
<td>201,390</td>
<td>107,983</td>
</tr>
<tr>
<td><strong>Total revenue and support</strong></td>
<td><strong>425,889,688</strong></td>
<td><strong>240,837,570</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Expenses</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program services:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>118,264,324</td>
<td>13,200,111</td>
</tr>
<tr>
<td>Contract management</td>
<td>6,926,202</td>
<td>6,459,361</td>
</tr>
<tr>
<td>Engagement, outreach, communication program development, science</td>
<td>18,717,862</td>
<td>14,179,921</td>
</tr>
<tr>
<td>Methodology</td>
<td>1,187,026</td>
<td>1,582,865</td>
</tr>
<tr>
<td><strong>Total expenses</strong></td>
<td><strong>145,095,414</strong></td>
<td><strong>35,422,258</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supporting services:</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative – general</td>
<td>15,943,471</td>
<td>11,610,860</td>
</tr>
<tr>
<td>Administrative – board</td>
<td>823,291</td>
<td>1,542,843</td>
</tr>
<tr>
<td><strong>Total expenses</strong></td>
<td><strong>161,862,176</strong></td>
<td><strong>48,575,961</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change in net assets</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in net assets</strong></td>
<td><strong>264,027,512</strong></td>
<td><strong>192,261,609</strong></td>
</tr>
</tbody>
</table>

Net Assets

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning</td>
<td>337,625,969</td>
<td>145,364,360</td>
</tr>
<tr>
<td><strong>Ending</strong></td>
<td><strong>$ 601,653,481</strong></td>
<td><strong>$ 337,625,969</strong></td>
</tr>
</tbody>
</table>

See Notes to Financial Statements.
## Patient-Centered Outcomes Research Institute

### Statements of Cash Flows
**For the Years Ended September 30, 2014 and 2013**

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash Flows From Operating Activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in net assets</td>
<td>$264,027,512</td>
<td>$192,261,609</td>
</tr>
<tr>
<td>Adjustments to reconcile change in net assets to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>1,575,135</td>
<td>807,176</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>652,475</td>
<td>131,855</td>
</tr>
<tr>
<td>Loss on disposal of property and equipment</td>
<td>-</td>
<td>9,552</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>(332,339,688)</td>
<td>(286,659,056)</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>16,736,150</td>
<td>(29,682,493)</td>
</tr>
<tr>
<td>Deposits and other assets</td>
<td>(700,477)</td>
<td>43,980</td>
</tr>
<tr>
<td>Increase in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable and accrued expenses</td>
<td>36,650,276</td>
<td>4,416,319</td>
</tr>
<tr>
<td><strong>Net cash used in operating activities</strong></td>
<td>(13,398,617)</td>
<td>(118,671,058)</td>
</tr>
<tr>
<td><strong>Cash Flow From Investing Activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(4,230,580)</td>
<td>(1,602,177)</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td>(4,230,580)</td>
<td>(1,602,177)</td>
</tr>
<tr>
<td><strong>Net decrease in cash</strong></td>
<td>(17,629,197)</td>
<td>(120,273,235)</td>
</tr>
<tr>
<td>Cash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beginning</td>
<td>25,063,381</td>
<td>145,336,616</td>
</tr>
<tr>
<td>Ending</td>
<td>$7,434,184</td>
<td>$25,063,381</td>
</tr>
</tbody>
</table>

See Notes to Financial Statements.
### Statement of Functional Expenses
For the Year Ended September 30, 2014

<table>
<thead>
<tr>
<th>Research</th>
<th>Methodology</th>
<th>Contract Management</th>
<th>Outreach, and Engagement</th>
<th>Science</th>
<th>Total Program Services</th>
<th>Administrative – Board</th>
<th>Administrative – General</th>
<th>Total Supporting Services</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>$118,264,324</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$118,264,324</td>
<td>$ -</td>
<td>$ -</td>
<td>$24</td>
<td>$24</td>
</tr>
<tr>
<td>Salaries and wages - other</td>
<td>-</td>
<td>-</td>
<td>1,152,346</td>
<td>2,433,220</td>
<td>6,827,550</td>
<td>10,413,116</td>
<td>-</td>
<td>3,681,601</td>
<td>3,681,601</td>
</tr>
<tr>
<td>Other professional services</td>
<td>-</td>
<td>101,971</td>
<td>2,522,768</td>
<td>829,786</td>
<td>3,935,369</td>
<td>7,389,894</td>
<td>146,175</td>
<td>5,456,465</td>
<td>5,602,640</td>
</tr>
<tr>
<td>Employee benefits/payroll taxes</td>
<td>-</td>
<td>-</td>
<td>115,314</td>
<td>245,695</td>
<td>737,647</td>
<td>1,098,656</td>
<td>55</td>
<td>2,969,755</td>
<td>2,969,810</td>
</tr>
<tr>
<td>Travel</td>
<td>-</td>
<td>159,907</td>
<td>1,002,289</td>
<td>267,613</td>
<td>764,030</td>
<td>2,193,839</td>
<td>171,058</td>
<td>434,627</td>
<td>605,685</td>
</tr>
<tr>
<td>Conferences, conventions, meetings</td>
<td>-</td>
<td>736,566</td>
<td>864,747</td>
<td>148,663</td>
<td>117,631</td>
<td>1,867,607</td>
<td>162,922</td>
<td>168,747</td>
<td>331,669</td>
</tr>
<tr>
<td>Depreciation an amortization</td>
<td>-</td>
<td>-</td>
<td>128,779</td>
<td>271,921</td>
<td>763,003</td>
<td>1,163,703</td>
<td>-</td>
<td>411,432</td>
<td>411,432</td>
</tr>
<tr>
<td>Rent, parking, other occupancy</td>
<td>-</td>
<td>-</td>
<td>119,037</td>
<td>251,351</td>
<td>705,285</td>
<td>1,075,673</td>
<td>-</td>
<td>380,310</td>
<td>380,310</td>
</tr>
<tr>
<td>Temporary Help</td>
<td>-</td>
<td>-</td>
<td>134,065</td>
<td>5,239</td>
<td>11,361</td>
<td>150,665</td>
<td>-</td>
<td>743,242</td>
<td>743,242</td>
</tr>
<tr>
<td>Reviewer services</td>
<td>-</td>
<td>394</td>
<td>796,569</td>
<td>760</td>
<td>14,609</td>
<td>812,332</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Telephone and communications</td>
<td>-</td>
<td>1,357</td>
<td>65,289</td>
<td>52,158</td>
<td>48,947</td>
<td>167,751</td>
<td>45,523</td>
<td>319,626</td>
<td>365,149</td>
</tr>
<tr>
<td>Board/Committee compensation</td>
<td>-</td>
<td>184,846</td>
<td>-</td>
<td>-</td>
<td>184,846</td>
<td>287,256</td>
<td>-</td>
<td>287,256</td>
<td>472,102</td>
</tr>
<tr>
<td>Legal fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>51,432</td>
<td>51,432</td>
<td>6,975</td>
<td>371,320</td>
</tr>
<tr>
<td>Accounting fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>269,278</td>
<td>269,278</td>
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<tr>
<td>Supplies</td>
<td>-</td>
<td>43</td>
<td>5,945</td>
<td>1,663</td>
<td>23,445</td>
<td>31,096</td>
<td>213</td>
<td>236,191</td>
<td>236,404</td>
</tr>
<tr>
<td>Equipment rental and maintenance</td>
<td>-</td>
<td>-</td>
<td>4,158</td>
<td>31</td>
<td>1,354</td>
<td>5,543</td>
<td>-</td>
<td>145,564</td>
<td>145,564</td>
</tr>
<tr>
<td>Advertising</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>85,225</td>
<td>10</td>
<td>85,235.00</td>
<td>32</td>
<td>53,445</td>
<td>53,477</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>25,680</td>
<td>45,493</td>
<td>71,173</td>
<td>-</td>
<td>63,317</td>
<td>63,317</td>
</tr>
<tr>
<td>Insurance - non-employee related</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>125,851</td>
<td>125,851</td>
</tr>
<tr>
<td>Books, subscriptions, references</td>
<td>-</td>
<td>-</td>
<td>803</td>
<td>33,232</td>
<td>13,750</td>
<td>47,785</td>
<td>-</td>
<td>52,325</td>
<td>52,325</td>
</tr>
<tr>
<td>Printing and copying</td>
<td>-</td>
<td>403</td>
<td>6,348</td>
<td>58</td>
<td>1,008</td>
<td>7,817</td>
<td>759</td>
<td>28,098</td>
<td>28,857</td>
</tr>
<tr>
<td>Postage and shipping</td>
<td>-</td>
<td>1,539</td>
<td>7,745</td>
<td>2,862</td>
<td>751</td>
<td>12,927</td>
<td>2,323</td>
<td>10,118</td>
<td>10,441</td>
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<tr>
<td>Bank/payroll fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>22,135</td>
<td>22,135</td>
</tr>
</tbody>
</table>

$118,264,324 $1,187,026 $6,926,202 $4,655,157 $14,062,705 $145,095,414 $923,291 $15,943,471 $16,766,762 $161,862,176

See Notes to Financial Statements.
## Patient-Centered Outcomes Research Institute
### Statement of Functional Expenses
**For the Year Ended September 30, 2013**

<table>
<thead>
<tr>
<th>Program Services</th>
<th>Supporting Services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research</strong></td>
<td><strong>Methodology</strong></td>
</tr>
<tr>
<td><strong>Contract</strong></td>
<td><strong>Outreach, and</strong></td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td><strong>Science</strong></td>
</tr>
<tr>
<td><strong>Communications,</strong></td>
<td><strong>Total Program</strong></td>
</tr>
<tr>
<td><strong>Service</strong></td>
<td><strong>Services</strong></td>
</tr>
<tr>
<td><strong>Supporting</strong></td>
<td><strong>Board</strong></td>
</tr>
<tr>
<td><strong>Services</strong></td>
<td><strong>Administrative</strong></td>
</tr>
<tr>
<td></td>
<td><strong>General</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Total Support</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>Services</strong></td>
</tr>
</tbody>
</table>

### General Expenses

<table>
<thead>
<tr>
<th>Category</th>
<th>Research</th>
<th>Methodology</th>
<th>Contract Management</th>
<th>Outreach, and Engagement</th>
<th>Science</th>
<th>Total Program Services</th>
<th>Administrative – Board</th>
<th>Administrative – General</th>
<th>Total Supporting Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other professional services</td>
<td>$13,200,111</td>
<td>-</td>
<td>$891,228</td>
<td>$4,335,112</td>
<td>$1,704,255</td>
<td>$3,406,180</td>
<td>$10,336,775</td>
<td>$383,304</td>
<td>$4,228,002</td>
</tr>
<tr>
<td>Research</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Salaries and wages – other</td>
<td>-</td>
<td>(49,894)</td>
<td>$615,430</td>
<td>$1,771,935</td>
<td>$3,410,418</td>
<td>$5,797,783</td>
<td>-</td>
<td>$3,022,470</td>
<td>$3,022,470</td>
</tr>
<tr>
<td>Employee benefits/payroll taxes</td>
<td>-</td>
<td>-</td>
<td>$328,556</td>
<td>$292,086</td>
<td>$470,642</td>
<td>-</td>
<td>-</td>
<td>$2,017,544</td>
<td>$2,017,544</td>
</tr>
<tr>
<td>Conferences, conventions, meetings</td>
<td>-</td>
<td>329,144</td>
<td>$579,054</td>
<td>$718,779</td>
<td>$147,869</td>
<td>$1,774,846</td>
<td>$383,969</td>
<td>(30,884)</td>
<td>$353,085</td>
</tr>
<tr>
<td>Travel</td>
<td>-</td>
<td>38,863</td>
<td>$500,238</td>
<td>$419,251</td>
<td>$373,997</td>
<td>$1,332,349</td>
<td>202,817</td>
<td>103,420</td>
<td>306,237</td>
</tr>
<tr>
<td>Rent, parking, other occupancy</td>
<td>-</td>
<td>-</td>
<td>1,175</td>
<td>$345,456</td>
<td>$229,110</td>
<td>$575,741</td>
<td>$356,094</td>
<td>$356,094</td>
<td>$912,188</td>
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<tr>
<td>Depreciation and amortization</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>109,068</td>
<td>$72,745</td>
<td>$162,413</td>
<td>-</td>
<td>624,745</td>
<td>624,745</td>
</tr>
<tr>
<td>Board/Committee compensation</td>
<td>-</td>
<td>248,685</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>489,076</td>
<td>25,000</td>
<td>514,076</td>
</tr>
<tr>
<td>Reviewer services</td>
<td>-</td>
<td>-</td>
<td>396,702</td>
<td>-</td>
<td>26,550</td>
<td>$176,547</td>
<td>$599,827</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Temporary help</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>158,781</td>
<td>$103,916</td>
<td>$262,687</td>
<td>-</td>
<td>$332,192</td>
<td>332,192</td>
</tr>
<tr>
<td>Legal fees</td>
<td>-</td>
<td>113</td>
<td>73,690</td>
<td>-</td>
<td>$5,425</td>
<td>$79,228</td>
<td>12,454</td>
<td>201,340</td>
<td>213,794</td>
</tr>
<tr>
<td>Accounting fees</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>258,169</td>
<td>258,169</td>
</tr>
<tr>
<td>Telephone and communications</td>
<td>-</td>
<td>1,970</td>
<td>1,289</td>
<td>71,756</td>
<td>30,715</td>
<td>105,730</td>
<td>18,281</td>
<td>109,330</td>
<td>127,611</td>
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<tr>
<td>Supplies</td>
<td>-</td>
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<td>1,568</td>
<td>54,513</td>
<td>35,726</td>
<td>102,039</td>
<td>9,297</td>
<td>99,305</td>
<td>108,602</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-</td>
<td>25,000</td>
<td>1,870</td>
<td>12,905</td>
<td>5,469</td>
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<td>-</td>
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<td>16,623</td>
<td>16,623</td>
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<td>2,783</td>
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<td>6,060</td>
<td>32,144</td>
<td>25,237</td>
<td>42,596</td>
<td>67,835</td>
</tr>
<tr>
<td>Books, subscriptions, references</td>
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<td>538</td>
<td>-</td>
<td>18,653</td>
<td>10,719</td>
<td>29,919</td>
<td>4,451</td>
<td>16,345</td>
<td>20,796</td>
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<tr>
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<td>-</td>
<td>2,895</td>
<td>-</td>
<td>4,815</td>
<td>-</td>
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<td>Insurance – non-employee related</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>46,776</td>
<td>46,776</td>
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<tr>
<td>Contracting capacity resources</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>40,665</td>
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<td>13,957</td>
<td>3,778</td>
<td>17,735</td>
</tr>
<tr>
<td>Bank/payroll fees</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>9,952</td>
<td>9,952</td>
</tr>
</tbody>
</table>

### Total

$$\text{Total Functional Expenses} = \text{Total Program Services} + \text{Administrative – Board} + \text{Administrative – General} + \text{Total Supporting Services}$$

$$\begin{align*}
\text{Total Functional Expenses} & = \text{Total Program Services} + \text{Administrative – Board} + \text{Administrative – General} + \text{Total Supporting Services} \\
& = 13,200,111 + 1,582,865 + 6,459,361 + 5,828,105 + 8,351,816 + 35,422,258 + 383,304 + 4,228,002 + 4,611,306 + 4,948,081 \\
& = 13,153,703 + 48,575,961
\end{align*}$$
Note 1. Nature of Activities and Significant Accounting Policies

Nature of activities: The Patient-Centered Outcomes Research Institute (PCORI) was authorized in 2010 by the Patient Protection and Affordable Care Act (42 U.S.C. 1301 et seq.) (Act) 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.” It does this by supporting comparative clinical effectiveness research (CER) projects designed to answer questions most important to patients. 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)(1) nonprofit corporation, governed by a 21-member multistakeholder Board of Governors, including 19 members appointed by the Comptroller General of the United States. 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). The Act also provides that the Directors of the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), or their designees, be members of the Board.

In accordance with the enabling legislation, Congress established the Patient-Centered Outcomes Research Trust Fund (PCORTF). In the fiscal year ending September 30, 2010, $1.26 billion was appropriated for the PCORTF; this funding is available through September 30, 2019, without further appropriation. Annual appropriations are deposited in November into the PCORTF as follows: $10 million in fiscal year 2010, $50 million in fiscal year 2011, and $150 million a year in each of the eight-fiscal years, 2012 through 2019. These amounts, less the annual 20% distribution to AHRQ and HHS beginning in fiscal year 2011, plus interest income, are available to PCORI as needed.

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 calendar year 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 the year ending September 30, 2013. For each fiscal year ending September 30 thereafter, 2014 through 2019, 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 fiscal years beginning after September 30, 2014, 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.

In the year ending September 30, 2013, the PCORTF began receiving the funding from the fees that will be imposed on certain health insurance and self-insured health plans. The fees will also be adjusted for increases in healthcare spending. The increase is a 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 capital of National Health Expenditures as most recently published by the Secretary before the beginning of the fiscal year.
Note 1. Nature of Activities and Significant Accounting Policies (Continued)

A summary of PCORI’s significant accounting policies follows:

**Fiscal period:** Historically, PCORI has reported its financial position, activities, and its cash flows on a calendar year basis. In calendar year 2013, the PCORI Board voted to change the financial reporting period for the corporation to a fiscal year that begins on October 1 and ends on September 30 of each year. Accordingly, the September 30, 2013 financial report presented audited financial statements covering the 12-month period ended December 31, 2012, and the 9-month period ending September 30, 2013. This September 30, 2014 financial report presents audited financial statements on a comparative basis for the 12-month periods ended September 30, 2014 and 2013. As such, the opening balances for the 2013 financial statements presented in this September 30, 2014 financial report (as of October 1, 2012) are different than those presented in the September 30, 2013 financial report (as of January 1, 2013).

**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, as applicable. PCORI had no temporarily restricted or permanently restricted net assets at September 30, 2014 and 2013.

**Property and equipment:** Property and equipment at September 30, 2014 and 2013, consisted of leasehold improvements, furniture, fixtures, equipment, and software. Purchases of personal 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.

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

**Deferred rent:** PCORI has various lease agreements for rental spaces in Washington, D.C. Under the terms of certain lease agreements, PCORI occupied office space for one to four months of free rent. The free month’s rent and escalating annual rent increases, in addition to a landlord improvement allowance, are being recognized on a straight-line basis over the life of the lease agreement and reflected as deferred rent in the accompanying statements of financial position.

**Revenue recognition:** Congress appropriated $1.26 billion for the PCORTF at the time of establishment. These federal appropriations are deemed to be earned and are recorded as revenue in the periods designated by Congress. The Act explicitly identified specific amounts and a period of attribution by fiscal year, beginning in October 2010 and ending in September 2019.
Note 1. Nature of Activities and Significant Accounting Policies (Continued)

In accordance with the legislation, beginning in fiscal year 2012, the Secretary of the Treasury provided for transfer to the PCORTF from the FHI Trust Fund and the FSMI Trust Fund in proportion to the total expenditures during such fiscal year that were made under title XVIII from the respective trust fund. The transfer amounts are provided by the CMS Budget and they are re-updated annually based on the published Mid-Session Review of the President’s Budget. The estimated transfers 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.

Patient-centered outcomes research (PCOR) fee revenue received is based on federal agency-generated estimates which are trued-up the following year based on IRS reconciliation of actual PCOR fee collections. Accounting standards dictate that estimates should be based on historical experience and other assumptions that are considered reasonable under given circumstances. Management is of the opinion that, given the complexity of the fee calculations, without historical perspective, estimates cannot be relied upon. To that end, PCOR fee revenue, is taken into revenue as it is received less an allowance until such a time as there is more historical perspective on which to evaluate the reliability of the estimates.

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 when the cost has been incurred. As of September 30, 2014 and 2013, research awards totaling $671 million and $181 million have been entered into, respectively. Prepayments on awards totaling $12,583,724 and $29,794,339 are included in prepaid expenses in the statements of financial position at September 30, 2014 and 2013, respectively.

Tax status: PCORI, a nonprofit organization incorporated in the District of Columbia and authorized by 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 to the extent that unrelated business income is generated. No provision for income taxes was required for the years ended September 30, 2014 and 2013, as PCORI has no unrelated business income revenue.

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

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

Financial and credit risk: The PCORTF was funded through congressional appropriation in fiscal year 2010 for the fiscal years 2010 through 2019. PCORI, HHS, and AHRQ are the only organizations that have access to the assets of the PCORTF.
Note 1. Nature of Activities and Significant Accounting Policies (Continued)

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

Audit requirements: PCORI is subject to financial and governmental oversight in accordance with its enabling legislation. PCORI is required to provide for the conduct of an annual financial audit through a private entity with experience in conducting financial audits. The Comptroller General of the United States is required to review the financial audit annually; the processes established by PCORI not less frequently than every five years; the dissemination/training activities and the data networks of PCORI not less frequently than every five years; the overall effectiveness of activities and the dissemination, training, and capacity-building activities conducted by PCORI not less frequently than every five years; and the adequacy and use of the funding for PCORI and the activities conducted no later than eight years after the date of enactment.

Subsequent events: PCORI evaluated subsequent events through March 3, 2015, 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 available to PCORI at September 30, 2014 and 2013, and activity in the Trust Fund for the years then ended, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance</td>
<td>$ 286,660,865</td>
<td>$ 1,808</td>
</tr>
<tr>
<td>Federal appropriations:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Fiscal Year Appropriation</td>
<td>150,000,000</td>
<td>150,000,000</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</td>
<td>57,870,000</td>
<td>27,265,000</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(11,574,000)</td>
<td>(5,453,000)</td>
</tr>
<tr>
<td>Transfers from FHI, November</td>
<td>49,097,000</td>
<td>24,730,000</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(9,819,400)</td>
<td>(4,946,000)</td>
</tr>
<tr>
<td>Patient-Centered Outcomes Research Fee</td>
<td>276,638,373</td>
<td>98,916,984</td>
</tr>
<tr>
<td>Less AHRQ and HHS share 20% of appropriation as mandated by statute</td>
<td>(56,523,675)</td>
<td>(19,783,397)</td>
</tr>
<tr>
<td>Interest earned</td>
<td>201,390</td>
<td>107,984</td>
</tr>
<tr>
<td>Other adjustment</td>
<td>-</td>
<td>486</td>
</tr>
<tr>
<td>Payments by PCORI</td>
<td>-</td>
<td>120,000,000</td>
</tr>
<tr>
<td>Draws by PCORI</td>
<td>(93,550,000)</td>
<td>(74,179,000)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$ 619,000,553</strong></td>
<td><strong>$ 286,660,865</strong></td>
</tr>
</tbody>
</table>
Note 2. Amounts Held by PCOR Trust Fund (Continued)

Amounts held by the PCORTF are placed in market-based overnight Treasury securities. These are Treasury securities whose interest rates or prices of which 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.

Note 3. Property and Equipment

Property and equipment and accumulated depreciation at September 30, 2014 and 2013, are as follows:

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leasehold improvements</td>
<td>$4,019,127</td>
<td>$2,175,379</td>
</tr>
<tr>
<td>Software development</td>
<td>2,404,230</td>
<td>1,033,260</td>
</tr>
<tr>
<td>Furniture, fixtures, and equipment</td>
<td>2,127,625</td>
<td>1,111,763</td>
</tr>
<tr>
<td></td>
<td>8,550,982</td>
<td>4,320,402</td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(2,593,181)</td>
<td>(1,018,046)</td>
</tr>
<tr>
<td></td>
<td><strong>5,957,801</strong></td>
<td><strong>3,302,356</strong></td>
</tr>
</tbody>
</table>

Note 4. Leases

PCORI has two noncancelable operating leases for office spaces in Washington, D.C. that expire on December 1, 2018 and February 29, 2020. During the years ended September 30, 2014 and 2013, leases were amended to include additional space. The landlords also contributed $506,450 and $86,520, respectively, to be used toward tenant improvements.

Future minimum rental payments applicable to the lease at September 30, 2014, are as follows:

<table>
<thead>
<tr>
<th>Year Ending September 30,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>$2,319,009</td>
</tr>
<tr>
<td>2016</td>
<td>2,462,749</td>
</tr>
<tr>
<td>2017</td>
<td>2,528,559</td>
</tr>
<tr>
<td>2018</td>
<td>2,596,338</td>
</tr>
<tr>
<td>2019</td>
<td>2,872,401</td>
</tr>
<tr>
<td>2020</td>
<td>1,149,921</td>
</tr>
<tr>
<td></td>
<td><strong>13,928,977</strong></td>
</tr>
</tbody>
</table>

Rent expense for the years ended September 30, 2014 and 2013, was $1,455,983 and $931,835, respectively.
Note 5. Financial Risks and Uncertainties

On March 1, 2013, the sequestration as required by the Budget Control Act of 2011 (BCA) and pursuant to section 215A 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 available funding to the PCORTF for obligations. Funds in sequester at September 30, 2014 and 2013, were $31,865,399 and $15,508,387 respectively. These funds were released from sequester and made available to the PCORTF for obligations on October 1, 2014 and 2013, respectively.

Note 6. Retirement Plan

Effective January 1, 2012, PCORI established the Defined Contribution Retirement Plan of the Patient-Centered Outcomes Research Institute. The Plan is intended to be a qualified plan under section 401(a) of the Internal Revenue Code of 1986, as amended, and it is a governmental plan as described in Code Section 414(d) and Section 3(32) of the Employee Retirement Income Security Act of 1974 (ERISA), as amended. All full-time regular employees are eligible to participate in the plan on the first day of the month following the date he or she becomes an eligible employee. PCORI matches employees’ contributions up to 5% of the participant’s eligible compensation. Additionally, PCORI makes a non-elective contribution of 5% of the participant’s eligible compensation. Participants are fully vested after one year of continuous employment with PCORI. Contribution expenses totaled $1,279,976 and $565,229 for the years ended September 30, 2014 and 2013, respectively.

Note 7. Commitments and Contingencies

PCORI is involved in various claims and disputes arising in the ordinary course of business. The ultimate disposition of these claims and disputes is not expected to have a material adverse effect on PCORI’s financial statements.

Note 8. Subsequent Events

On September 30, 2014, PCORI announced 46 research projects totaling $102 million. The contracts for these projects will be executed in FY 2015.

On December 8, 2014, PCORI approved providing up to $50 million for up to four comparative clinical effectiveness research (CER) studies on the best ways to diagnose and treat hepatitis C virus infection.
Independent Auditor’s Report on Internal Control Over Financial Reporting
and on Compliance and Other Matters Based on an Audit of Financial
Statements Performed in Accordance With Government Auditing Standards

To the Audit and Conflict of Interest Sub-Committee of the Governance
Committee of the Board of Governors
Patient-Centered Outcomes Research Institute
Washington, D.C.

We have audited, in accordance with the 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, the financial statements of Patient-Centered Outcomes Research Institute (PCORI), which comprise the statement of financial position as of September 30, 2014, the related statements of activities, cash flows, and functional expenses for the year then ended and the related notes to the financial statements, and have issued our report thereon dated March 3, 2015.

Internal Control Over Financial Reporting
In planning and performing our audit of the financial statements, we considered PCORI’s internal control over financial reporting (internal control) to determine the audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements, but not for the purpose of expressing an opinion on the effectiveness of PCORI’s internal control. Accordingly, we do not express an opinion on the effectiveness of PCORI’s internal control.

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

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

Compliance and Other Matters
As part of obtaining reasonable assurance about whether PCORI’s financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the determination of financial statement amounts. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under Government Auditing Standards.
Purpose of This Report
The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the entity's internal control or on compliance. This report is an integral part of an audit performed in accordance with Government Auditing Standards in considering the entity's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Gaithersburg, Maryland
March 3, 2015
PATIENT-CENTERED OUTCOMES RESEARCH (PCOR)*

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:

• Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?

• What are my options and what are the potential benefits and harms of those options?

• What can I do to improve the outcomes that are most important to me?

• 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:

• 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;

• is inclusive of an individual’s preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;

• incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and

• investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

*Approved by PCORI Board of Governors March 5, 2012