"Patient-centered research empowers patient populations to share their personal experiences to inform the design and real-world application of research."

Vanessa Boulanger, MSc
Director of Research Programs, National Organization for Rare Disorders

This report covers PCORI activities and results for fiscal year 2018, October 1, 2017 through September 30, 2018.
Leadership Letter

On behalf of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, Methodology Committee, and staff, we are pleased to present this report on PCORI’s achievements and activities during the October 1, 2017-September 30, 2018 fiscal year (FY).

This was a very productive year for PCORI, marked by steady progress in continuing to meet the mandates Congress set for us in 2010 to fund comparative clinical effectiveness research (CER) that will help patients and those who care for them make better-informed healthcare decisions. You will read more about our work in the pages that follow.

In addition to noting these achievements and related initiatives PCORI has pursued in FY 2018, this year’s Annual Report also tells the stories of some of these projects, giving you a look at the people—the researchers and their patient and other stakeholder partners—behind the research.

Because at the end of the day, it is their efforts, and those of many others across the healthcare community, that make it possible for us to generate useful, trustworthy information about which care and treatment options work best for whom.

We look forward to FY 2019 being an even more productive year for PCORI, as scores of additional funded studies are completed and produce results that can help fill the gaps in evidence needed to improve patient care and outcomes. We are confident that we will continue to show all our stakeholders—including Congress—the value of the public investment in the work we have done to date and the promise of deriving even greater value from our groundbreaking approach to research in the future.

As always, we invite your thoughts on everything we do.

Joe V. Selby, MD, MPH
Executive Director

Grayson Norquist, MD, MSPH
Chairperson, PCORI Board of Governors

A Few Highlights

- A growing collection of results from the patient-centered CER studies funded under our National Priorities for Research and Research Agenda. These studies focus on many of the conditions that impose the greatest burdens on patients, their families, and the healthcare system.
- A large portfolio of innovative projects designed to advance the dissemination and implementation of the findings of several dozen of our completed studies.
- Ongoing refinement in our groundbreaking efforts to engage patients and other healthcare stakeholders in all the work we do, from identifying research topics to study to promoting the adoption of promising results in practice.
- A surge in the number of professional and lay-language summaries posted on our website following completion of our mandated peer-review process. We also provide links to research results tables posted on ClinicalTrials.gov highlighting the results of our funded studies, along with some two dozen full final research reports.
- Continued progress in demonstrating the research capacity of PCORnet®, the National Patient-Centered Clinical Research Network, which was initiated in 2013 to improve the nation’s capacity to conduct patient-centered health research more efficiently and with greater power than had been possible before.
PCORI at Age Eight: 
An Update on Progress and Promise

Patients work with their doctors to make choices about care every day in medical offices, clinics, and hospitals across our nation. Other healthcare stakeholders do the same. All want to know which treatment or care options might be best for particular patients so they can make the most informed decisions possible. Too often, though, those decisions are made in the absence of complete or relevant evidence.

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 to address this problem. A private, nonprofit organization guided by stakeholders across the healthcare community, PCORI funds studies designed to produce reliable, useful information that helps patients, family caregivers, clinicians, employers, insurers, policy makers, and others make better-informed healthcare choices.

We are now documenting examples of how PCORI-funded studies can help patients choose care that is right for them and improve their health outcomes.

These pages reveal a sampling of the dozens of research results revealed in fiscal year (FY) 2018.

► Chronic pain disproportionately affects people with less education and low incomes. A study found that such patients were able to more effectively manage chronic pain after receiving simplified versions of either cognitive behavioral therapy (CBT) or pain education compared to those who got usual pain care. Pain education and CBT offer nondrug approaches to help manage chronic pain, a condition associated with an alarming surge in opioid use disorders.

► A study found the finger sticks that many people with non-insulin-dependent type 2 diabetes do daily to check their blood sugar levels achieve no significant differences in disease control, hospitalization rates, need to start using insulin, or quality of life.

► Another study tested a program called I-PASS that included parents as active participants in pediatric unit rounds at eight hospitals to determine whether it would improve hospital safety. The program reduced harmful medical errors—preventable adverse events—by 39 percent.
Funded Projects by Area

<table>
<thead>
<tr>
<th>Area</th>
<th>Funding</th>
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</thead>
<tbody>
<tr>
<td>Comparative Clinical Effectiveness Research</td>
<td>$1.9 Billion</td>
</tr>
<tr>
<td>Infrastructure (including PCORnet)</td>
<td>$377 Million</td>
</tr>
<tr>
<td>Methodology Research</td>
<td>$133 Million</td>
</tr>
</tbody>
</table>

These figures represent PCORI funding of projects from FY 2010 through FY 2018.

PCORI’s Research Priorities and Agenda

Our National Priorities for Research and Research Agenda guided all of our 2018 work, as they have from PCORI’s beginning.

**Assessment of Prevention, Diagnosis, and Treatment Options**
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.

**Improving Healthcare Systems**
Comparing health system-level approaches to improving access, supporting patient self-care, innovating the use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

**Communication and Dissemination Research**
Comparing approaches to providing comparative effectiveness research (CER) information, empowering people to ask for and use the information, and supporting shared decision making between patients and their providers.

**Addressing Disparities**
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.

**Accelerating Patient-Centered Outcomes Research and Methodological Research**
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.

See the complete National Priorities for Research and Research Agenda at [www.pcori.org/national-priorities](http://www.pcori.org/national-priorities).
Better Research through Engagement

At the heart of PCORI’s work is our commitment to involving patients and other healthcare stakeholders, including caregivers, researchers, clinicians, insurers, health systems, policy makers, and employers, every step of the way. We engage patients and other stakeholders in all aspects of our work and require our funded researchers to do the same.

We are seeking to ensure that we are asking the right research questions, studying the outcomes that matter most to patients, and producing useful and relevant results that are more likely to be used in practice.

Ways We Engage

RESEARCH TOPIC DEVELOPMENT
We involve patients, caregivers, clinicians, and other members of the healthcare community in identifying and selecting topics.

MERIT REVIEW
We recruit and train patients and other stakeholders to review applications for PCORI research funding.

ENGAGEMENT IN RESEARCH
We provide technical support and resources to research teams to ensure stakeholders are involved meaningfully throughout a project’s life cycle, and our five advisory panels bring voices from across the healthcare community into our work, including representatives of practicing and research clinicians, patients, as well as experts in health services research, health services delivery, and evidence-based medicine.

DISSEMINATION
We work with stakeholders to communicate findings and promote their use in practice through Dissemination and Implementation Awards and cobranding efforts that involve nonprofit organizations, health systems, and others.

“Instead of saying, ‘Here’s what we think researchers and patients need,’ we said, ‘Let’s ask the patients.’”

Linda Burns, MD
Vice President and Medical Director of Health Services Research at the National Marrow Donor Program
Disseminating and Implementing Results

Medical research faces multiple challenges when communicating scientific advances, including presenting results in formats or language that patients and their caregivers can readily understand and navigating a years-long process from results to practical application.

PCORI is taking proactive steps to accelerate the dissemination and implementation of scientific findings. Our Patient-Centered Outcomes Research Translation Center works with researchers to produce easy-to-read summaries for patients and the public describing research results and separate summaries for healthcare clinicians with study details and findings.

We prepare Evidence Updates in concise, accessible formats and deliver them in partnership with patient organizations and others.

To improve access to important research findings, we require our supported researchers to place papers in PubMed Central, a repository for free access to final accepted manuscripts, generally 12 months after publication.

Elements of Dissemination and Implementation

- Is the evidence ready for use? Does it respond to stakeholders’ concerns?
- Who will benefit from this evidence? Who can help reach that audience?
- How can we make the evidence available?
- What information about the evidence will people need?
- How can we support adoption? What strategies will lead to widespread implementation?
- How will the effectiveness of our strategies be assessed? What data do we need?

Engagement of Individuals, Communities, Organizations, and Agencies
FY 2018 Milestones

October
- PCORI’s third Annual Meeting emphasizes the importance of generating evidence that will transform practice, sharing research results, engaging patients in interpreting scientific findings and their real-world relevance, and enhancing public access to research outcomes.
- The Board of Governors approves $9 million for a new study comparing two approaches to relieving noncancer chronic pain and reducing opioid use.

November
- Board authorizes $57 million to support 14 new CER studies involving dementia care, prostate cancer treatment, human papillomavirus vaccine use, and more.

December
- PCORI makes up to $40 million available for CER on treatment options for pediatric anxiety disorders and another $1.4 million for disseminating and implementing useful findings from completed PCORI-funded studies.

March
- The US Government Accountability Office (GAO) issues a review of how PCORI uses funds available through the Patient-Centered Outcomes Research Trust Fund to advance its mission. The report, which makes no recommendations for improvement, cites comments from stakeholders supporting our work and its potential use in practice.
- As part of its commitment to transparency, PCORI posts the first peer-reviewed final research report from a completed study, with 20 to follow in FY 2018.

April
- Board approves new funding totaling $74 million to support research on the treatment of opioid use disorders, obesity, and other CER topics, including $10 million to support research on medication-assisted treatment for pregnant women with opioid use disorders.
- Board approves four projects to foster relationships between researchers and partner networks participating in PCORnet and outside organizations to support research using PCORnet resources.
- Board adopts new Methodology Standards, for a total of 54 Standards.

June
- PCORI and American Heart Association collaborate to award $5 million to establish center to support better-informed AFib treatment decisions.

August
- Board names 33 people to serve on multistakeholder advisory panels.
- Board approves $85 million for new studies comparing two or more approaches to improve care and outcomes for a range of conditions.

September
- PCORI and Agency for Healthcare Research and Quality collaborate to commit $40 million over five years to 11 institutions to train researchers to conduct patient-centered outcomes research (PCOR) within learning health systems.
- GAO appoints seven stakeholders from across the healthcare community to fill open seats on the Board.
- Board approves data management and data sharing policy calling for PCORI-funded researchers to share their de-identified data sets and documentation to facilitate reproduction of original analyses and enable additional research analyses.
FY 2018 Snapshot

**Generating Evidence**

$308 million in awards, including 39 CER studies, five methods studies, and 10 PCORnet infrastructure projects

A total of 492 articles about PCORI-funded research appeared in scientific journals. CER results were reported in 336 articles

122 professional and lay-language result summaries of our completed projects and 21 final research reports posted on our website

**Achieving Impact**

13 Dissemination and Implementation Awards totaling $16.3 million

28 citations of results from PCORI-funded studies appear in evidence-based clinical recommendations

PCORI-funded models suggest applying results of four key studies could reduce the burden key conditions impose on patients, families, employers, and the healthcare system

Board adopts updated Methodology Standards

$15 million approved for 72 Engagement Awards

**Influencing Others**

Results of our funded studies used as a basis for a Centers for Medicare and Medicaid Services national coverage decision on implantable cardiac defibrillators and influenced Commission on Accreditation of Rehabilitation Facilities accreditation standards

PCORI credited as part of the inspiration for a Patient Engagement Advisory Committee at the Food and Drug Administration’s Center for Devices and Radiological Health

"Many new drugs coming on the market are quite expensive. We just don’t know how well these new medicines work compared with existing or alternative therapies. We need comparative clinical effectiveness research to better understand how these treatments work in the real world and whether they yield better outcomes over time."

Lawrence Becker
PCORI Board of Governors Member
Again in FY 2018, PCORI experienced steady growth in the number of our funded projects generating results to help patients and those who care for them make better-informed healthcare decisions.

Generating evidence on how to better treat high-burden, high-impact conditions is only useful if those results get into the hands of those who need them most. That’s why we post professional and lay-language summaries of the results of all of our completed research and links to the research results tables on ClinicalTrials.gov on our website. We have posted a total of more than 100 sets of such results, and another 150 are moving through the pipeline. Further, results from dozens of our funded studies have been reported in articles in leading medical journals.

For an organization that is still relatively young, our research portfolio is producing results at an ever-increasing rate. And we continue to fund more research.

In FY 2018, PCORI awarded $238 MILLION TO FUND 39 new comparative clinical effectiveness research studies

The theme of our third Annual Meeting, Delivering Results, Informing Choices, allowed us to focus on results from our funded projects. Highlights of three such studies follow and provide a taste of the promising results our supported researchers are generating.
Using the Brain to Fight Chronic Pain

Chronic pain is a high-burden health problem, particularly among socioeconomically disadvantaged people. Compared to the general population, these individuals have a higher incidence of chronic pain and less access to pain treatment.

Certain pain education interventions and CBT had previously been shown to reduce chronic pain’s intensity and impact. But these interventions had mainly been tested on literate, middle-class patients. PCORI-funded researcher Beverly Thorn, PhD, of the University of Alabama, wanted to determine whether tailoring the education and CBT interventions to better fit underserved populations would produce positive results for those patients.

The study divided its 300 participants—most of whom live below the poverty threshold and have limited reading ability—into three sets (usual care only; usual care with group pain education; and usual care with group CBT that includes pain education). Thorn adapted standard CBT practices and patient materials, as well as the group education materials, for this population. The research team evaluated the participants immediately before and after 10 weeks of group treatments, and six months after those treatments ended.

The results were very encouraging. Compared with people who received usual care, those who received group sessions of either type reported lower pain intensity at the end of the sessions. People who attended education or therapy sessions also reported better physical function than people receiving usual care. Depression symptoms eased in people who attended group sessions.

Thorn’s results may provide a blueprint for addressing the disparity that people with low socioeconomic status face in treating chronic pain. PCORI champions projects that target high-burden conditions and underserved populations, and this one addresses both aims.

"Early on, when I visited one of the pain clinics where we conducted the study, the head physician said to me, 'Dr. Thorn, what are you doing to my patients? They’re coming in, smiling at me, teaching me about chronic pain. This is magic!' That was so gratifying to hear."

Beverly Thorn, PhD
Comparing Effectiveness, Safety of Bariatric Surgery Options

People with obesity have options when looking for the treatment approach that might work. But for those seeking a surgical solution, choosing the right treatment can be as complex as the condition itself.

Results from the PCORnet Bariatric Study are helping point the way to the best solution. The project was one of the first designed to test the capabilities of PCORnet, the National Patient-Centered Clinical Research Network, which has been developed with PCORI funding. PCORnet securely harnesses networks of clinical information from millions of patients to help conduct large-scale health research more efficiently and quickly at a lower cost than otherwise possible.

The research team, led by David Arterburn, MD, MPH, of Kaiser Permanente Washington Health Research Institute, compared outcomes of patients who underwent one of three bariatric surgical procedures: Roux-en-Y gastric bypass, adjustable gastric banding, and sleeve gastrectomy. All three procedures reduce the amount of food a person can eat before feeling full.

Researchers analyzed outcomes of 65,000 adult patients and 544 adolescent patients who underwent one of the three bariatric procedures, checking their status at one, three, and five years after their surgeries. They reported that adults who underwent Roux-en-Y gastric bypass lost more weight than adults who had the other two procedures at one, three, and five years postsurgery, but the Roux-en-Y group also was more likely to have an adverse event in the 30 days postsurgery than the other groups. This detailed evidence can help patients make decisions based on their own circumstances and preferences.

Through its use of PCORnet, this study was completed in just two years, much faster than would otherwise be possible.

“"In my experience, research has only had one role for patients in a study: as subjects. In this study, patients were partners in the research process."

Neely Williams, MDiv
Patient Co-investigator
Transforming Care Access and Delivery through Telehealth

Psoriasis is a chronic autoimmune skin disease affecting nearly 7 million Americans. As with many chronic diseases, access to specialized care is crucial, and can be a barrier for people who live far from providers or who have trouble traveling to an appointment. So, a PCORI-funded research team led by April Armstrong, MD, MPH, of the University of Southern California, investigated whether online care—commonly called telehealth—could be an effective alternative to in-person care.

Their study randomly divided nearly 300 patients from California and Colorado into two groups: one saw dermatologists in person as usual, and the other—along with their primary care physicians—had online access to dermatologists who provided assessments, recommendations, education, and prescriptions. Researchers found that patients in the online program saw just as much improvement in their condition as those who received in-person care at a clinic. Patients in the online group also saved time and other costs associated with traveling to and from appointments.

This study adds to mounting evidence supporting the potential for telehealth to make specialty care more accessible to those who need it.

For more highlights of our funded research portfolio, visit www.pcori.org/results.

“Instead of having a patient go to the location of care, we are trying to bring care to the patients. I hope you will see that this model has the potential of being transformative and potentially applicable to other areas of medicine.”

April Armstrong, MD, MPH
ACHIEVING IMPACT

Striving to make it easier for patients, caregivers, and other stakeholders to reach decisions about health care is at the center of our work. We do this by funding patient-centered outcomes research, but also by promoting the rapid acceptance and use of PCORI-funded research findings to improve healthcare practice and health outcomes.

Twenty-eight new citations of our funded research results appeared in evidence-based clinical recommendations in FY 2018, bringing our cumulative total to 39 citations. These are clinical guidelines on topics such as type 2 diabetes and stroke management that list relevant articles containing results from our funded studies as supporting these standards of care. Articles with results from our funded studies have also been cited on pages dedicated to specific medical topics, including the prevention of adverse drug events in hospitals and prescription drug misuse. Many of these citations appear in the same online resources that healthcare providers and patients rely on when making care decisions.

Several high-impact projects continued to the next level of PCORI support by earning Dissemination and Implementation Awards. This funding provides for the expansion of projects, their findings, and their interventions, making it possible to reach an even greater number of patients, caregivers, and healthcare providers. Three of those original research projects centered on patient- and family-centered rounds for hospitalized children, treatment for chest pain, and non-insulin-treated type 2 diabetes.

Uptake into Evidence-Based Clinical Recommendations

- **ELEVEN CITATIONS OF PCORI RESULTS IN UPTODATE®**
  Topics of results cited include prescription drug misuse, prostate cancer treatment, pneumonia in children, and self-monitoring of blood glucose.

- **NINE CITATIONS OF PCORI RESULTS IN DYNAMED PLUS™**
  Topics of results cited include chest pain in the emergency department, peripheral arterial disease, bariatric surgery, and posttraumatic stress disorder.

- **EIGHT CITATIONS OF PCORI RESULTS IN EVIDENCE-BASED CLINICAL RECOMMENDATIONS**
  Topics of results cited include prostate cancer treatment, transgender health, and chronic heart failure diagnosis and management.
Rethinking Management for Type 2 Diabetes

The Monitor study, which compared the effects of using three approaches for daily self-monitoring of blood sugar levels in patients with non-insulin-treated type 2 diabetes, will expand its reach to additional sites within the University of North Carolina Physicians Network.

The original study randomly placed patients into one of three groups:

- Individuals who didn't check their blood sugar levels daily
- Patients who monitored their blood sugar levels daily and received immediate results
- Participants, who along with daily self-monitoring and immediate results, received text messages that explained what their levels may mean

Principal Investigator Katrina Donahue, MD, MPH, of the University of North Carolina at Chapel Hill and her research team did not find differences in blood sugar control between those patients who checked their levels daily and those who did not after 12 months. The team also found no differences in patients' health-related quality of life, including between those patients who received text messages about their blood sugar levels and those who did not.

A Dissemination and Implementation Award approved in 2018 will further support this project by spreading awareness of its findings and implementing its program, Rethink the Strip, at additional primary care practices. The program has the potential to affect more than 4,000 patients with non-insulin-treated type 2 diabetes being treated by network physicians.

The Monitor project was one of four chosen in FY 2018 to be the subject of PCORI-funded impact modeling of how broadly implementing the studies' results might benefit patients and the healthcare system. In this case, the model assumed the findings could be applied across the estimated 7.1 million people aged 30 and older in the United States who perform an average of 5.4 self-tests per week. Doing so over five years, it suggested, could avoid 10 billion blood glucose tests—and finger sticks—with the average patient saving approximately $1,600 in testing supply costs.

“The Monitor Trial is the first large trial of blood sugar control, blood sugar testing in patients with type 2 diabetes not on insulin in the United States.”

Katrina Donahue, MD, MPH
Putting Families and Patients at the Center of Hospital Rounds

A PCORI-funded project that demonstrated the effectiveness of making hospital medical rounds more patient- and family-centered will extend its intervention to 18 diverse pediatric academic and community hospitals in 16 states with the support of a Dissemination and Implementation Award.

The original study tested the effectiveness of Patient- and Family-Centered I-PASS, an intervention that emphasizes family engagement, health literacy, and interprofessional and nurse engagement in hospital medical rounds, compared to the usual care that physicians used during their hospital rounds. The goal of the I-PASS approach is to improve communication and reduce the incidence of medical errors and adverse events in hospitalized children.

Although the overall rate of errors was unchanged, Principal Investigator Christopher Landrigan, MD, MPH, of Boston Children’s Hospital and his team found that I-PASS yielded a 38 percent decrease in harmful medical errors—characterized as preventable adverse events. Researchers also reported improved nurse and family engagement on rounds, as well as an increased frequency of families expressing concerns at the start of rounds.

The project’s expansion could potentially improve patient-centered care for 48,000 patients and their families each year. This includes reducing adverse events while improving communication among clinicians and families.

“About half of all serious medical errors that occur are due to miscommunications—either miscommunications amongst the medical team or between the medical team, patients, and families. This project is targeting those specific types of errors.”

Christopher Landrigan, MD, MPH
Helping People with Chest Pain Make the Right Decision for Them

Every year more than 8 million people in the United States visit the emergency department because they are experiencing chest pain, but a significant percentage are not having a heart attack or other serious heart problem. Researchers conducting a PCORI-funded study found that using a questionnaire called Chest Pain Choice proved effective in helping such individuals decide whether to forgo unnecessary hospital stays and intensive medical tests.

The results of this original PCORI-funded study will broaden to five hospitals at three large health systems in Alabama, California, and Minnesota under a Dissemination and Implementation Award.

The study’s decision aid provided patients with information on their personal risk of a heart attack and helped them decide, with their clinicians, whether to stay in the emergency department for observation and further cardiac testing or to seek a referral for an outpatient evaluation.

Principal Investigator Erik Hess, MD, MS, of the Mayo Clinic and his team found that patients who used the decision aid and shared in the decision-making process with their healthcare providers had greater knowledge of their risk for a heart attack and better understood their options for care. Patients who made the decision with their clinician were less likely to decide to be admitted to the emergency department’s observation unit for cardiac testing.

Now, through PCORI funding, the decision aid will be built into the electronic medical record systems at five emergency departments at the Mayo Clinic, Kaiser Permanente Northern California, and the University of Alabama-Birmingham. The decision aid has the potential to improve patient-centered care for more than 30,000 patients who arrive at hospitals with chest pain.

This project also was the subject of a PCORI-funded impact model, which suggested that if the decision aid were in widespread use, 1.4 million people could choose not to stay in the hospital overnight for stress tests and cardiac imaging but could safely return for outpatient evaluation later. That could mean 800,000 fewer stress tests, $130 million in costs saved by patients, and $4.7 billion in costs saved by public and private payers over five years.

“In the ER, the level of stress and anxiety in patients is so high. You can’t begin to have discussions until they understand where they are in terms of risk.”

Annie LeBlanc, PhD
Caregiver
Bringing patients and other healthcare collaborators together to partner in all aspects of our work makes PCORI unique, and in turn, makes the results of our funded research uniquely impactful.

Our charge is also to spread the concept of a patient-inclusive approach to research to the broader healthcare community. Researchers and funders want more information about how best to incorporate engagement into their work. Several developments in FY 2018 vividly illustrate how we’re influencing the broader research community.

 Patients and Other Stakeholders Are Involved in...

- Helping determine Research Priorities
- Determining Research Partnerships and Capacity
- Helping determine Research Relationships and PCOR Skill Building
- Conducting Research Topic Solicitation and Input, Advisory Panels, and Workshops
- Conducting Research Research Teams
- Conducting Research Dissemination and Implementation
- Conducting Research Sharing and Uptake of Findings
- Conducting Research Impacting Institutional Policies and Clinical Practice

"PCORI has offered a way for caregivers, including siblings like myself, to have a seat at the table."

Eunice Im
Cofounder of the California Sibling Leadership Network, a caregiver for a sibling with autism, and a PCORI peer reviewer
Evidence of Our Influence

Major stakeholders in the healthcare landscape are taking note of our work. Citing influence from PCORI’s Advisory Panel on Patient Engagement, the Food and Drug Administration has committed to including the views of patients during the medical device development process and is also considering patient perspectives in its regulatory decision making.

The PCORI Engagement Rubric also guided the Centers for Medicare and Medicaid Services in its efforts to partner with patients to develop quality measures.

We see further evidence in the eight-year review of our work completed this year by the GAO. Its report notes that stakeholders told the office, “PCORI’s efforts to engage patients in the research process have changed the way research is conducted for the better, such as prioritizing research outcomes that are most meaningful to patients.”

We also track the use of the PCORI Methodology Standards. We’ve observed more than 170 citations of the methodology standards in published literature through FY 2018, which is one measure that our influence on patient-centered outcomes research is spreading.

Finally, major hospitals and universities have cited PCORI as an impetus for developing CER centers, CER awards programs, and patient and community advisory boards to inform research. In one example, Debra Fiser, MD, of the University of Arkansas for Medical Sciences said PCORI’s approach inspired her to establish a center for patient-centered CER. We’re also increasingly seeing CER included in academic curriculum development and in health literature, both in the form of patient-centered language to make medical journals more digestible to lay audiences and the inclusion of patient reviewers on medical journal editorial boards.
The Power of Patients in the Review Process

While other funders include patients and other stakeholders in their processes for reviewing applications, PCORI fully integrates them. We are unique in requiring patients and stakeholders on all teams that review the merit of applications for our research funding, and they are also now participating in peer-reviewing our completed studies, assessing a wide range of criteria.

As we closed FY 2018, we had new evidence to support our conviction that PCORI’s inclusive process results in stronger funded research, thanks to an internal evaluation of reviewer surveys, review scores, and focus groups.

The primary factor for whether an application receives our funding is its scientific merit. However, reviewers say our inclusive process frequently results in increased attention to often-overlooked factors, including how useful a study’s results could be to patients, plans for engaging with patients as partners throughout the research process, and discussions about whether a proposal’s expectations of patients or clinicians in research were feasible and realistic.

Improving Our Engagement Plan

In FY 2018, we also published an update to our Engagement Plan template, a roadmap to help new awardees turn the engagement plans in their funding applications into a real-world blueprint once a project is underway. While the updated Engagement Plan is required for new PCORI awardees, the takeaways and webinar have proven to be relevant to anyone seeking to engage patients and other collaborators in research plans.

The updated plan also helps us examine the relationship between engagement activities and study outcomes.

“Well-designed CER can give patients and other healthcare decision makers, including payers, the information they need to confidently choose treatments that will improve health and reduce disparities.”

Trent Haywood, MD, JD
Chief Medical Officer for the Blue Cross Blue Shield Association; Member, PCORI Board of Governors
**Engagement Awards**

In addition to influencing other organizations to be patient centered, we continue to operate our Eugene Washington PCORI Engagement Awards program, which funds projects that enable organizations to engage patients, caregivers, clinicians, and others as partners in research. The past year saw new categories of Engagement Awards, including one reflecting our increased emphasis on disseminating PCORI-funded published results and evidence. PCORI approved 72 Engagement Awards totaling $15.1 million in FY 2018, bringing the program's cumulative totals to 332 awards for $67.3 million.

We are enthusiastic about our influence in spreading a patient-centered way of doing research across the healthcare community. While more work remains to be done, our commitment to putting patients at the heart of all we do is helping transform our nation's research and health efforts.

**ENGAGEMENT AWARD CATEGORIES**

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<th>CAPACITY BUILDING</th>
<th>CONFERENCE SUPPORT</th>
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<td>UP TO $300,000</td>
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<td>UP TO 2 YEARS</td>
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“PCORI’s funding of this project allowed me and others a vehicle by which we can find more people who are like us and who can go from being unemployed and unemployable to full-time productive lifestyles.”

Sonya Ballentine
Patient Partner, PCORI-funded Engagement Award on mental health
Looking Ahead

This past year brought significant achievements to PCORI. Scores of our funded studies were completed with more expected in the coming year, adding to the growing body of evidence to improve care and patient outcomes. And we look forward to reaching more milestones in FY 2019 as the patient-centered outcomes research community continues to grow, along with its impact and influence.

We plan to invest more than $400 million in research and other initiatives by the end of FY 2019. We’ll also work closely with our stakeholders to increase the specificity of our pipeline of research topics that can lead to studies expanding the evidence base on key questions of concern to them.

As results from many more of our funded studies become available, we will expand our focus on making those findings available to the public as widely and quickly as possible and promoting the use of this information in practice. This is especially true when we consider the many new—and typically high-cost—therapies and technologies that hit the market with little or no information on comparative effectiveness.

Our continuum of information products will expand to include:

**Evidence maps**
These visual representations of evidence available on specific research topics will provide a clear picture of the current research landscape on areas of interest.

**Horizon scans**
The Health Care Horizon Scanning System provides a systematic process to identify healthcare interventions that have high potential to alter the current standard of care.

**Emerging technologies and therapeutics reports**
These will provide timely summaries of evidence supporting new drugs, devices, and other healthcare technologies that are recently in use or may be available in the near term in the United States.

Our funded rapid-cycle research projects are small observational studies designed to quickly address stakeholder-prioritized research questions. We have funded several that are underway through PCORnet, on topics such as diagnostic or treatment options for cancer, diabetes, heart disease, and hepatitis C virus infection, and one to assess the feasibility of future stakeholder-prioritized research. More of these studies will begin in 2019.

As we have since our founding, PCORI will pursue its work with the help of our stakeholders whose guidance is at the center of all that we do.
Administrative and Governance Update

As a learning organization, PCORI is committed to analyzing and evaluating its efforts to ensure ongoing improvement in the quality of its work and in the efficiency and effectiveness of its operations. This past year we took several steps to meet our strategic goals and the mandates of our authorizing legislation.

Board of Governors Updates Our Governance Framework

The PCORI Board of Governors experienced a significant transition in FY 2018, with the departure of six members who had completed their terms. We thanked these departing members who ably served PCORI since its inception, and also welcomed seven new members appointed by GAO in September 2018. In addition, GAO appointed Christine Goertz, who has served on PCORI’s Board since September 2010, as the Board’s new vice chairperson. These changes usher in an exciting new chapter in PCORI’s story.

Because all Board members serve on PCORI’s strategy or other committees, new committee chairs and vice chairs were appointed to fill vacancies created by the departure of former Board members, and each newly appointed member was assigned to a committee where they can gain a fuller understanding of PCORI’s work.

In FY 2018, the Board of Governors approved amendments to the PCORI bylaws and other governing documents to align with DC nonprofit law, PCORI’s authorizing law, and good governance.

The amendments to the bylaws clarified provisions relating to quorum requirements when a member departs the Board prior to the end of his or her term; updated language concerning authority of committees to use terminology in the DC nonprofit law; and aligned provisions relating to Board and Methodology Committee appointments to GAO’s historic approach and interpretation of its appointment authority.

The Board approved several amendments to the charters of some committees. The charter for the Engagement, Dissemination, and Implementation Committee (EDIC) was amended to add responsibility for overseeing PCORI's scientific publishing strategy and related activities, given that the Board sunset the Scientific Publications Committee, which previously oversaw these activities. The Board also approved amendments to the Governance Committee Charter that allow for members of the Governance Committee to serve as a chair or vice chair of another committee.
**Board Adopts New Methodology Standards**

Developing and improving the science and methods of patient-centered outcomes research is a central part of PCORI's work. Better methods will produce more valid, trustworthy, and useful information that will lead to better healthcare decisions and, ultimately, to improved patient outcomes.

In April 2018, at the recommendation of the Methodology Committee, the Board of Governors adopted an additional six Methodology Standards: five new standards on studies of complex interventions and one standard for data management plans. At the conclusion of FY 2018, PCORI's Methodology Standards provided guidance in 13 topic areas, for a total of 54 standards.

**GAO Report Reviews PCORI Activities**

Under our authorizing law, the US Comptroller General is required to review PCORI's activities at least every five years and at eight years. GAO’s eight-year review, released in March 2018, was a straightforward description of our activities, with no agency recommendations for improvement.

We were pleased that most stakeholders quoted in the GAO report recognized PCORI's leadership in changing the way health research is conducted by engaging patients and prioritizing research outcomes most meaningful to them. And we were excited that stakeholders highlighted the importance of disseminating the findings of our funded studies quickly, in ways readily available and understandable to experts and the public.

This is a welcome follow-up to the GAO’s 2015 review of our work, which found that we were meeting the mandates of our authorizing law as of that date.

**New Office Supports Business Efficiency and Effectiveness Efforts**

PCORI established the Program Support and Information Management Office in January 2018 to provide leadership in business processes and award management operations, as well as enterprise information management in support of our funding programs. The team's duties include supporting the scientific integrity of merit review, transparency and accountability of awards and contracts management, and the efficient stewardship of information resources.

Among the immediate tasks were restructuring contract management functions, completing the initial buildup of a dedicated data quality and assurance function, and funding operations support capacity. The office also performed foundational work on an internal PCORI data warehouse that will include analytical, reporting, and data visualization tools.

**Annual Meeting Draws Patients, Researchers, and Other Stakeholders**

Our third Annual Meeting, held in the fall of 2017, convened nearly 1,000 patients, caregivers, advocates, researchers, clinicians, health system and industry representatives, and other stakeholders.

The meeting theme, *Delivering Results, Informing Choices*, was reflected in some two dozen sessions where attendees heard about results from PCORI's earliest-funded CER studies and efforts to promote the use of those important findings in practice. They also discussed key trends in patient-centered outcomes research and connected with colleagues to share ideas for future research opportunities.

We used a number of digital tools to extend the meeting's reach. Hundreds of people who could not attend in person watched presentations via webcast and Facebook Live. The meeting also generated some 8,500 tweets reaching 31 million Twitter users during and after the event.
## Appendices

### FY 2018 Actual and FY 2019 Budget

**Note:** Our authorizing law requires that our Annual Report include PCORI’s budget for the year following the period covered by the report. The independent audit of our FY 2018 financial report, provided to Congress by the US Government Accountability Office, is available at [www.pcori.org/about-us/financials-and-reports](http://www.pcori.org/about-us/financials-and-reports).

<table>
<thead>
<tr>
<th>FY 2018 Actual</th>
<th>FY 2019 Budget</th>
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</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
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<tr>
<td><strong>Expenses</strong></td>
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<td>Program Services</td>
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<td>Administrative Expenses</td>
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<td><strong>Total Expenses</strong></td>
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<td>Change in Net Assets before Unrealized Gain/Loss on Short-term Investments</td>
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</tr>
<tr>
<td>Change in Net Assets before Unrealized Gain/Loss on Short-term Investments</td>
<td>$164,682,208</td>
</tr>
</tbody>
</table>

### FY 2018 Awards Funding Commitment (Awards Approved)

**TOTAL:** $308 Million

- **83.2%**
  - $256 Million
  - RESEARCH
- **6.8%**
  - $21 Million
  - DISSEMINATION AND IMPLEMENTATION
- **5.2%**
  - $16 Million
  - RESEARCH INFRASTRUCTURE
- **4.8%**
  - $15 Million
  - ENGAGEMENT

### FY 2019 Awards Funding Commitment (Planned)

**TOTAL:** $279 Million

- **67%**
  - $187 Million
  - RESEARCH
- **10.4%**
  - $29 Million
  - DISSEMINATION AND IMPLEMENTATION
- **11.8%**
  - $33 Million
  - RESEARCH INFRASTRUCTURE
- **10.8%**
  - $30 Million
  - ENGAGEMENT
# 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. Disclosures reflect those reported to PCORI as of April 4, 2019.

## BOARD OF GOVERNORS

### Kara Ayers, PhD  
(As of January 30, 2019)

**Financial Associations**
- Amgen, Stock  
- Bristol-Myers Squibb, Stock  
- CVS Health, Stock  
- Gilead Sciences, Stock, Spouse  
- GlaxoSmithKline, Stock  
- Health Care Select SPDR, Stock, Spouse  
- Humana, Inc., Stock, Spouse  
- Johnson and Johnson, Stock  
- LSB Consultants, LLC, Employer, Spouse  
- Medtronic, Stock, Spouse  
- Pfizer, Inc., Stock, Spouse  
- SPDR Biotech, Stock, Spouse  
- The Traveler’s Companies, Inc., Stock  
- United Health Group, Stock, Spouse  
- University of Rochester Medical Center, Employer, Sibling  
- VanEck Vectors Biotech ETF, Stock, Spouse  
- Xerox Corporation, Retired, Self

**Personal Associations**
- Jewish Senior Life, Board Member  
- Rochester RHIO, Board Chair  
- SpineIQ, Board Member

### Jennifer DeVoe, MD, MPhil, MCR, DPhil, FAAFP  
(As of February 21, 2019)

**Financial Associations**
- Agency for Healthcare Research and Quality (AHRQ), Receive Research Funding  
- American Board of Family Medicine, Exam Writer (Honorarium for Meetings)  
- National Health, Lung, and Blood Institute, National Advisory Committee Member (Stipend for Meetings)  
- National Institutes of Health (NHBLI, NCI), Receive Research Funding  
- Oregon Community Health Information Network (OCHIN), Research Advisor  
- Oregon Health and Science University, Employer  
- People-Centered Research Foundation (PCRF), Receive Infrastructure Funding  
- Virginia Commonwealth University, CTSA External Advisory Group Member (Honorarium for Meetings)

**Personal Associations**
- American Academy of Family Physicians  
  - Annals of Family Medicine Journal External Advisory Board Member  
  - Family Medicine for America’s Health Board Member  
- American Board of Family Medicine, Journal of the American Board of Family Medicine, Editorial Advisory Board  
- Mayo Clinic Proceedings Journal, Family Medicine Section Editor  
- Montana State University Honors College, External Advisory Board Member  
- National Academies of Science, Engineering and Medicine  
  - Health and Medicine Division, Health Care Services Board Member  
  - Committee on Applying Neurobiological and Socio-behavioral Sciences from Prenatal to Early Childhood Development: A Health Equity Approach, Committee Chair  
- Puffer Fellow Selection Committee Member  
- North American Primary Care Research Group, Committee Member

### Lawrence Becker  
(As of February 22, 2019)

**Financial Associations**
- Amgen, Stock  
- Bristol-Myers Squibb, Stock  
- CVS Health, Stock  
- Gilead Sciences, Stock, Spouse  
- GlaxoSmithKline, Stock  
- Health Care Select SPDR, Stock, Spouse  
- Humana, Inc., Stock, Spouse  
- Johnson and Johnson, Stock  
- LSB Consultants, LLC, Employer, Spouse  
- Medtronic, Stock, Spouse  
- Pfizer, Inc., Stock, Spouse  
- SPDR Biotech, Stock, Spouse  
- The Traveler’s Companies, Inc., Stock  
- United Health Group, Stock, Spouse  
- University of Rochester Medical Center, Employer, Sibling  
- VanEck Vectors Biotech ETF, Stock, Spouse  
- Xerox Corporation, Retired, Self

**Personal Associations**
- Jewish Senior Life, Board Member  
- Rochester RHIO, Board Chair  
- SpineIQ, Board Member

### Francis S. Collins, MD, PhD  
(As of January 14, 2019)

**Financial Associations**
- National Institutes of Health, Employer  
- National Academy of Medicine, Member  
- National Academy of Sciences, Member

**Personal Associations**
- Institute of Medicine Roundtable on Literacy, Member  
- National Hispanic Medical Association, Member  
- Society of General Internal Medicine, Council Member, Active Volunteer

### Christopher Friese, PhD, RN, AOCN, FAAN  
(As of April 4, 2019)

**Financial Associations**
- Merck Foundation, Receive Research Funding  
- Robert Wood Johnson Foundation, Consultant  
- RTI International, Consultant  
- University of Michigan, Employer  
- Cancer Nursing, Standing Reviewer

**Personal Associations**
- Quality Insights of Pennsylvania, Consultant  
- RAND Corporation, Consultant  
- Spine IQ, Employer  
- University of Iowa, Faculty

### Christine Goertz, DC, PhD  
(Vice Chairperson)  
(As of January 21, 2019)

**Financial Associations**
- American Chiropractic Association, Consultant  
- Christine Goertz LLC, Owner, Self and Spouse  
- Duke University, Consultant  
- Healthwise, Inc., Consultant  
- Mount Sinai Medical Center, Consultant  
- National Institutes of Health, Advisory Board Member (Compensated Position)  
- Palmer College of Chiropractic, Consultant  
- Quality Insights of Pennsylvania, Consultant  
- RAND Corporation, Consultant  
- Spine IQ, Employer  
- University of Iowa, Faculty

**Personal Associations**
- American Chiropractic Association, Member  
- American Public Health Association, Member  
- Chiropractic and Manual Therapies, Editorial Board Member  
- Drake University, College of Pharmacy and Health Sciences, Active Volunteer, Spouse  
- Journal of Manipulative and Physiological Therapeutics, Editorial Board Member  
- World Federation of Chiropractic, Board Member

### Alicia Fernandez, MD  
(As of January 14, 2019)

**Financial Associations**
- University of California, San Francisco, Employer  
- Prosetta Bioconformatics, Stock

**Personal Associations**
- Institute of Medicine Roundtable on Literacy, Member  
- National Hispanic Medical Association, Member  
- Society of General Internal Medicine, Council Member, Active Volunteer

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*Personal Associations*  
*Financial Associations*  
*(As of January 14, 2019)*  
*(As of February 22, 2019)*  
*(As of January 30, 2019)*  
*(As of April 4, 2019)*  
*(As of January 21, 2019)*  
*(As of January 14, 2019)*
Trent Haywood, MD, JD  
(As of March 4, 2019)  
Financial Associations  
• Blue Cross Blue Shield Association, Employer  
Personal Associations  
• YMCA, Board Member  
Michael Herndon, DO  
(As of October 19, 2018)  
Financial Associations  
• Oklahoma Health Care Authority, Employer  
Personal Associations  
• Medicaid Medical Directors Network, Member  
Russell Howerton, MD  
(As of January 31, 2019)  
Financial Associations  
• Wake Forest University Health Sciences, Employer  
Personal Associations  
• Cornerstone Health Enablement Strategic Solutions (CHESS), Board Officer  
Gail Hunt  
(As of March 5, 2019)  
Financial Associations  
• None Reported  
Personal Associations  
• American Society on Aging, Member  
• Center for Aging Services Technology, Commissioner  
• Coalition to Transform Advanced Care (C-TAC), Member  
• Gerontological Society of America, Member  
• Long Term Quality Alliance, Board Secretary  
• NQF Measure Application Partnership Coordinating Committee, Member  
• NQF Patient and Family Centered Care Committee on Quality Measurement, Chair  
Gopal Khanna, MBA  
(As of February 5, 2019)  
Financial Associations  
• Agency for Healthcare Research and Quality, Employer  
Personal Associations  
• Pathways to Children, Board of Directors Member  
Sharon Levine, MD  
(As of February 28, 2019)  
Financial Associations  
• Southern California Permanente Medical Group, Inc., Employer  
Personal Associations  
• California Medical Association Foundation, Obesity Prevention Project, Board Member, Spouse  
• Institute for Medical Quality, Board Member  
Freda Lewis-Hall, MD  
(As of January 31, 2019)  
Financial Associations  
• Bristol-Myers Squibb, Retirement Plan  
• Bristol-Myers Squibb, Stock, Self and Spouse  
• Eli Lilly and Company, Pension Plan, Self and Spouse  
• Pfizer, Inc., Employer  
• Pfizer, Inc., Savings Plans and Retirement Plan  
• Tenet, Former Board Member  
• Vertex Pharmaceuticals, Stock and Retirement Plan  
Personal Associations  
• Dell Medical School, Board Member  
• FasterCures, Board Member  
• Foundation for the National Institutes of Health, Board Member  
• Harvard Medical School, Board Member  
Michelle McMurry-Heath, MD, PhD  
(As of December 10, 2018)  
Financial Associations  
• Johnson and Johnson, Employer; Stock  
Personal Associations  
• National Evaluation System and Health Technology (NEST), Governing Committee Chair  
Barbara J. McNeil, MD, PhD  
(As of January 3, 2019)  
Financial Associations  
• Blue Cross and Blue Shield Association, Medical Advisory Panel Member  
• Brigham and Women's Hospital/ Harvard Medical School, Employer  
• Edwards Lifesciences, Stock  
• Harvard University Medical School, Employer  
• Marine Polymer Technologies, Board of Directors/Trustees (Compensated Position)  
• Marine Polymer Technologies, Consultant  
Personal Associations  
• AGMednet, Board Member (Non-compensated Position)  
• American Academy of Arts and Sciences, Member  
• American Association for the Advancement of Science, Fellow  
• American College of Radiology, Member  
• American Medical Association, Member  
• CMS Imaging Efficiency Measures Technical Panel, Member  
• Massachusetts Medical Society, Member  
• National Academy of Medicine, Member  
• Society for Medical Decision Making, Member  
• Society of Nuclear Medicine and Molecular Imaging, Member  
Grayson Norquist, MD, MSPH (Chairperson)  
(As of December 20, 2018)  
Financial Associations  
• Emory University, Employer  
Personal Associations  
• AcademyHealth, Fellow  
• American Psychiatric Association Council on Quality Care, Chair, Fellow  
• University of Mississippi Medical Center, Former Employer  
Ellen Sigal, PhD  
(As of January 28, 2019)  
Financial Associations  
• iShares Core S&P Midcap ETF, Stock, Jointly  
• iShares MSCI EAFE ETF, Stock, Jointly and Spouse  
• iShares MSCI, Japan New, Stock, Self and Spouse  
• iShares Russell 1000 Growth ETF, Stock, Self and Spouse  
• iShares Russell 1000 Value ETF, Stock, Spouse and Jointly  
• SPDR S&P 500 Trust ETF, Stock, Jointly and Self and Spouse  
Personal Associations  
• DC Students Constructions Trades Foundation, Board Member, Child  
• Duke University Cancer Center, Board of Overseers  
• Foundation for the National Institutes of Health, Board Member  
• Friends of Cancer Research, Board Officer  
• George Washington University Medical Center, Advisory Council Member (Non-compensated Position), Spouse  
• George Washington University Milken Institute School of Public Health, Advisory Board Member  
• George Washington University, Medical Faculty Associates Board of Trustees, Spouse  
• MD Anderson Cancer Center, Advisory Board Member  
• New York University Faculty of Arts and Science, Board of Overseers, Spouse  
• NYU-DC Steering Committee, Board Member, Spouse  
• Parker Institute for Cancer Immunotherapy, Advisory Board Member  
• Reagan-Udall Foundation, Board Officer  
• Sidney Kimmel Comprehensive Cancer Center Advisory Council, Advisory Council Member (Non-compensated Position)  
• Stand Up 2 Cancer (SU2C) Catalyst Executive Committee, Committee/Work Groups Member  
• Stand Up 2 Cancer, Committee/Work Groups Member
### METHODOLOGY COMMITTEE

#### Naomi Aronson, PhD
(As of February 1, 2019)

**Financial Associations**
- None Reported

**Personal Associations**
- American Society for Clinical Oncology, Member
- The Alliance for Clinical Trials in Oncology Foundation, Board Officer

#### Ethan Basch, MD, MSc
(As of January 8, 2019)

**Financial Associations**
- Carevive, Advisory Board Member (Compensated Position)
- Journal of the American Medical Association, Editor
- Memorial Sloan-Kettering Cancer Center, Consultant
- Sivan Healthcare, Advisory Board Member (Compensated Position)
- University of North Carolina, Chapel Hill, Employer

**Personal Associations**
- American Society of Clinical Oncology, Board Member
- The Alliance for Clinical Trials in Oncology Foundation, Board Officer

#### Stephanie Chang, MD, MPH
(As of December 21, 2018)

**Financial Associations**
- Agency for Healthcare Research Quality, Employer

**Personal Associations**
- American College of Physicians, Guest of High Value Care Coordination Task Force
- Arlington Free Clinic, Volunteer Physician
- Guidelines International Network, Trustee

#### David Flum, MD, MPH
(As of December 27, 2018)

**Financial Associations**
- Benchmark Medical, LLC, Consultant
- Surgical Consulting LLC, Expert Testimony

**Personal Associations**
- International Society for Pharmacoeconomics and Outcomes Research, Member
- International Society for Quality of Life, Member
- International Society of Pharmacoepidemiology, Board Member and Fellow

#### Janet Woodcock, MD
(As of February 21, 2019)

**Financial Associations**
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Employer

**Personal Associations**
- New England Journal of Medicine, Editorial Board Member

#### Robert Zwolak, MD, PhD
(As of January 31, 2019)

**Financial Associations**
- ISPE, CER Special Interest Group, ICPE Education Committee, Member
- Merck and Co., Inc., Former Employer
- University of North Carolina, Dept. of Epidemiology, Adjunct Professor

#### Steven Goodman, MD, MHS, PhD
(Vice-Chair)
(As of January 31, 2019)

**Financial Associations**
- Stanford University, Employer

**Personal Associations**
- American College of Physicians, Editorial Board Member, Associate Editor
- National Blue Cross Blue Shield Technology, Evaluation Center, Medical Advisory Panel, Advisory Board Member
- Society for Clinical Trials, Member

#### Mark Helfand, MD, MS, MPH
(As of February 1, 2019)

**Financial Associations**
- Oregon Health and Science University, Faculty
- Blue Cross and Blue Shield Association, Consultant
- VA Portland Health Care System, Grantee

**Personal Associations**
- Academy/Health Annual Research Meeting, Member
- American College of Physicians, Member
- Society for Medical Decision Making, Member
- U.S. Cochrane Center, Director

#### Michael S. Lauer, MD
(As of December 21, 2018)

**Financial Associations**
- Johns Hopkins University, Employer, Spouse
- National Institutes of Health, Employer
-Putnam College Fund, Investments
- Savings Investment Plan, Investments, Self and Spouse
-UptoDate, Inc., Employer, Spouse

**Personal Associations**
- None Reported
David O. Meltzer, MD, PhD  
(As of January 31, 2019)

Financial Associations
- Acadia Pharmaceuticals, Stock
- Agency for Healthcare Research and Quality (AHRQ), Grant
- American Board of Internal Medicine, Board of Directors/Trustees (Compensated Position)
- Center for Medicare and Medicaid Innovation (CMMI), Grant
- National Institutes of Health, Grant
- PCORI, Contract
- Richmond Foundation, Grant
- Robert Wood Johnson (RWJ) Foundation, Grant
- U.S. Food and Drug Administration (FDA), Grant
- University of Chicago, Employer

Personal Associations
- Society of General Internal Medicine, Member

Brian S. Mittman, PhD  
(As of January 26, 2019)

Financial Associations
- Cedars-Sinai Medical Center, Consultant
- Cedars-Sinai Medical Center, Employer, Spouse
- Department of Veterans Affairs Palo Alto, Consultant
- Duke University, Advisory Board Member (Compensated Position)
- Geisinger Center for Health Research, Advisory Board Member (Compensated Position)
- Johns Hopkins School of Medicine, Employer, Sibling
- Kaiser Permanente Southern California, Employer
- Merck, Speaker
- Northwestern University Feinberg School of Medicine, Advisory Board Member (Compensated Position)
- Oregon Health and Science University, Advisory Board Member (Compensated Position)
- RTI International, Employer, Child
- UCLA School of Medicine, Consultant
- University of Colorado Denver, Advisory Board Member (Compensated Position)
- University of Kentucky College of Medicine, Advisory Board Member (Compensated Position)
- University of Maryland Baltimore School of Pharmacy, Advisory Board Member (Compensated Position)
- USC, Consultant
- Washington University in St. Louis, Consultant

Personal Associations
- American Association of Medical Colleges, Advisory Council Member (Non-compensated Position)
- Kings College London Centre for Implementation Science/CLAHRS South London, Advisory Board Member
- St. Michael’s Hospital/University of Toronto, Advisory Council Member (Non-compensated Position)

Sally C. Morton, PhD  
(As of December 25, 2018)

Financial Associations
- University of Pittsburgh, Consultant
- Virginia Tech University, Employer

Personal Associations
- Agency for Healthcare Research and Quality, Advisory Council Member (Non-compensated)
- American Association for the Advancement of Science, Member
- American Statistical Association, Committee/Work Group Member
- Caucus for Women in Statistics, Member
- National Collaborative on Gun Violence Research, Advisory Board Member
- RAND Corporation, Former Employer
- RTI International, Former Employer
- Society for Research Synthesis Methodology, Member
- University of Pittsburgh, Former Employer

Robin Newhouse, PhD, RN (Chair)  
(As of January 3, 2019)

Financial Associations
- American Nurses Association, Book Author
- Indiana University School of Nursing, Employer

Personal Associations
- AcademyHealth, Board Officer and Member
- American Academy of Nursing, Member
- American Nurses Association, Member
- National Academy of Medicine, Member

Neil R. Powe, MD, MPH, MBA  
(As of January 3, 2019)

Financial Associations
- American Society of Nephrology, Editor
- Centers for Disease Control and Prevention, Grants
- University of California at San Francisco, Employer

Personal Associations
- AcademyHealth, Member
- American Clinical and Climatological Association, Member

Adam Wilcox, PhD  
(As of February 1, 2019)

Financial Associations
- HCR-ManorCare, Employer, Sibling
- Kaiser Permanente Washington Health Research Institute, Consultant
- University of Washington, Employer
- UW Medicine, Employer
- VA Portland Health Care System, Speaker

Personal Associations
- AcademyHealth, Committee/Work Group Member
- Agency for Healthcare Research and Quality (AHRQ), Committee/Work Group Member
- American Board of Preventive Medicine, Exam Committee, Committee/Work Group Member
- American Medical Informatics Association, Member
- eGEMs (Generating Evidence and Methods to improve patient outcomes), Editorial Board Member
- National Institutes of Health, Committee/Work Group Member
PCORI EXECUTIVE STAFF

Joe V. Selby, MD, MPH
(As of March 18, 2019)
Financial Associations
• Kaiser Permanente Medical Center San Francisco, Employer, Child
Personal Associations
• Clinical Trials Transformation Initiative (CTTI), Board Member
• Medical Device Innovations Consortium (MDIC), Board Member
• SPOR, Canadian Institutes of Health Research, Board Member

Mary C. Hennessey, Esq.
(As of June 1, 2018)
Financial Associations
• None Reported
Personal Associations
• American Health Lawyers Association, Member
• U.S. Department of Health and Human Services Advisory Council on Blood Stem Cell Transplantation, Member

Michele J. Orza, ScD
(As of June 12, 2018)
Financial Associations
• None Reported
Personal Associations
• National Academy of Medicine, Committee Member
• U.S. Food and Drug Administration, Committee Member

Jean R. Slutsky, PA, MSPH
(As of May 24, 2018)
Financial Associations
• None Reported
Personal Associations
• None Reported

Evelyn P. Whitlock, MD, MPH
(Left the Executive Staff on June 8, 2018 but remained on PCORI Staff)
(As of June 22, 2018)
Financial Associations
• None Reported
Personal Associations
• Agency for Healthcare Research and Quality, Former Director of Kaiser Permanente Research Affiliates Evidence-based Practice Center, an AHRQ-designated and funded center
• Kaiser Permanente Northwest Health Plan and Hospitals, Former Employer

Diane Bild, MD, MPH
(Joined the Executive Staff on April 1, 2018)
(As of June 13, 2018)
Financial Associations
• National Cancer Institute, Employer, Spouse
Personal Associations
• None Reported

Regina L. Yan, MA
(As of May 29, 2018)
Financial Associations
• None Reported
Personal Associations
• None Reported

Yen-pin Chiang, PhD
(As of May 23, 2018)
Financial Associations
• None Reported
Personal Associations
• None Reported

Mary C. Hennessey, Esq.
(As of June 1, 2018)
Financial Associations
• None Reported
Personal Associations
• American Health Lawyers Association, Member
• U.S. Department of Health and Human Services Advisory Council on Blood Stem Cell Transplantation, Member

Michele J. Orza, ScD
(As of June 12, 2018)
Financial Associations
• None Reported
Personal Associations
• National Academy of Medicine, Committee Member
• U.S. Food and Drug Administration, Committee Member

Jean R. Slutsky, PA, MSPH
(As of May 24, 2018)
Financial Associations
• None Reported
Personal Associations
• None Reported

Note: Conflict of interest disclosure statements for all PCORI staff are available at www.pcori.org/people.

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.

PCORI PEER REVIEWERS

Names of the individuals contributing to any PCORI peer-review process and their conflict of interest disclosure statements are available at www.pcori.org/research-results/peer-review/who-are-our-peer-reviewers.
## Approved Research Awards

*Contracts awarded October 1, 2017 to September 30, 2018*

### PCORnet Research Infrastructure Awards

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<th>PROJECT TITLE</th>
<th>ORGANIZATION</th>
<th>PRINCIPAL INVESTIGATOR</th>
<th>AMOUNT AWARDED</th>
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<td>People-Centered Research Foundation</td>
<td>Kathy Hudson</td>
<td>$16,000,000</td>
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<td>Improving Outcomes in Limited Juvenile Idiopathic Arthritis</td>
<td>Duke University</td>
<td>Laura Schanberg</td>
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<td>Using PCORnet to Compare Blood Pressure Control Strategies</td>
<td>The Regents of the University of California, San Francisco</td>
<td>Mark Pletcher</td>
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<td>Comparative Effectiveness of Pharmacogenomics for Treatment of Depression (CEPIO-D)</td>
<td>Massachusetts General Hospital (The General Hospital Corp.)</td>
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<td>Comparative Effectiveness of Biologic or Small Molecule Therapies in IBD</td>
<td>The University of North Carolina at Chapel Hill</td>
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<tr>
<td>Identifying and Predicting Patients with Preventable High Utilization</td>
<td>Joan and Sanford I. Weill Medical College of Cornell University</td>
<td>Rainu Kaushal</td>
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<td>Collaborative Research Group – Cancer</td>
<td>University of Kansas Medical Center Research Institute</td>
<td>Lemuel Waitman</td>
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<td>Collaborative Research Group – Kidney</td>
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<td>Michelle Denburg</td>
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<td>Collaborative Research Group – Diabetes and Obesity</td>
<td>Vanderbilt University Medical Center</td>
<td>Russell Rothman</td>
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<td>Collaborative Research Group – Pulmonary</td>
<td>COPD Foundation, Inc.</td>
<td>Barbara Yawn</td>
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<td>Collaborative Research Group – Health Disparities</td>
<td>Oregon Community Health Information Network (OCHIN), Inc.</td>
<td>Jon Puro</td>
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<td>Collaborative Research Group – Health Policy and Public Health</td>
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<td>Collaborative Research Group – Autoimmune</td>
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<td>Collaborative Research Group – Pediatric</td>
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<td>Christopher Forrest</td>
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## Cycle 3 2016 Contracts

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<tr>
<td>Integrated Health Services to Reduce Opioid Use While Managing Chronic Pain</td>
<td>RTI International</td>
<td>Lauren McCormack</td>
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## Cycle 1 2017 Contracts

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<tr>
<td>Comparative Effectiveness of Health System-Based versus Community-Based Dementia Care</td>
<td>David Geffen School of Medicine at UCLA</td>
<td>David Reuben</td>
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<td>A Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Prostate Cancer</td>
<td>University of Florida</td>
<td>Nancy Mendenhall</td>
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<td>Optimizing Treatment Sequencing for Patients with Chronic, Non-Specific Low Back Pain</td>
<td>University of Utah</td>
<td>Julie Fritz</td>
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<td>Comparative Effectiveness of System Interventions to Increase HPV Vaccine Receipt in FQHCs</td>
<td>University of California, Los Angeles</td>
<td>Roshan Bastani</td>
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<td>A Comparative Effectiveness Trial of an Information Technology Enhanced Peer-Integrated Collaborative Care Intervention for US Trauma Care Systems</td>
<td>University of Washington</td>
<td>Douglas Zatzick</td>
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<td>Comparison of Patient-Centered versus Provider-Centered Delivery of Cognitive Behavioral Treatment (CBT) for Pediatric Anxiety and Obsessive Compulsive Disorder (OCD)</td>
<td>Emma Pendleton Bradley Hospital</td>
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<td>Comparative Effectiveness of Mindfulness-Based Stress Reduction and Pharmacotherapy for Anxiety</td>
<td>Georgetown University</td>
<td>Elizabeth Hoge</td>
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<td>Promoting Autonomy and Improving Shared Decision-Making for Older Adults with Advanced Kidney Disease</td>
<td>Tufts University</td>
<td>Keren Ladin</td>
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<td>Reducing Health Disparities for Black Women in the Treatment of Insomnia</td>
<td>Trustees of Boston University, BUMC</td>
<td>Lynn Rosenberg</td>
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<td>Comparative Effectiveness Research to Improve the Health of Sexual and Gender Minority (SGM) Patients Through Cultural Competence and Skill Training of Community Health Center (CHC) Providers and Non-Clinical Staff</td>
<td>Fenway Community Health Center</td>
<td>Ken Mayer</td>
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<td>Transgender Cohort Study of Gender Affirmation and HIV-Related Health</td>
<td>Harvard Medical School, Boston Children's Hospital</td>
<td>Sari Reisner</td>
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<td>Comparative Effectiveness of Clinical Decision-Making Processes Required by Public Health Systems</td>
<td>RTI International</td>
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<td>Randomized Controlled Trial of Laser Hair Depilation in Adolescents with Pilonidal Disease</td>
<td>Nationwide Children's Hospital</td>
<td>Peter Minneci</td>
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<td>Unlocking Clinical Text in EMR by Query Refinement Using both Knowledge Bases and Word Embedding</td>
<td>The Research Institute at Nationwide Children's Hospital</td>
<td>Simon Lin</td>
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<td>Advancing Privacy Preserving Record Linkage Methods in the Context of Real-World Data Networks and HIE</td>
<td>Trustees of Indiana University</td>
<td>Shaun Grannis</td>
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## Cycle 2 2017 Contracts

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<td>A Pragmatic Family Centered Approach to Childhood Obesity Treatment</td>
<td>Washington University</td>
<td>Denise Wilfley</td>
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<td>KIDS FACE FEARS: Face-to-Face versus Computer-Enhanced Formats Pragmatic Study of Anxiety</td>
<td>Boston Medical Center Corporation</td>
<td>Lisa Fortuna</td>
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<td>Multilevel Interventions for Increasing Tobacco Cessation at FQHCs</td>
<td>University of Utah</td>
<td>David Wetter</td>
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<td>Improving Outcomes in Limited Juvenile Idiopathic Arthritis</td>
<td>Duke University</td>
<td>Laura Schanberg</td>
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<td>Integrated Physical and Mental Health Self-management Compared to Chronic Disease Self-Management</td>
<td>Dartmouth-Hitchcock Clinic</td>
<td>Stephen Bartels</td>
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<td>Using PCORnet to Compare Blood Pressure Control Strategies</td>
<td>The Regents of the University of California, San Francisco</td>
<td>Mark Pletcher</td>
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<td>Multicenter Randomized Pragmatic Clinical Trial Comparing Two- versus Three-Antibiotic Therapy for Pulmonary Mycobacterium Avium Complex Disease</td>
<td>Oregon Health and Science University</td>
<td>Kevin Winthrop</td>
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<td>Comparative Effectiveness of Pharmacogenomics for Treatment of Depression (CEPIO-D)</td>
<td>Massachusetts General Hospital (The General Hospital Corp.)</td>
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<td>Moms in Recovery (MORE): Defining Optimal Care for Pregnant Women and Infants</td>
<td>Trustees of Dartmouth College</td>
<td>Sarah Lord</td>
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<td>Comparative Effectiveness of Two State Payer Strategies to Prevent Unsafe Opioid Prescribing</td>
<td>University of Washington</td>
<td>Gary Franklin</td>
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<td>The PATH Home Trial: A Comparative Effectiveness Study of Peripartum Opioid Use Disorder in Rural Kentucky</td>
<td>University of Kentucky Research Foundation</td>
<td>Agatha Critchfield</td>
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<td>Personalized Treatments for Depressive Symptoms in Patients with Advanced Heart Failure</td>
<td>Cedars-Sinai Medical Center</td>
<td>Waguih Ishak</td>
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<td>Comparative Effectiveness of Biologic or Small Molecule Therapies in IBD</td>
<td>The University of North Carolina at Chapel Hill</td>
<td>Michael Kappelman</td>
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<td>Comparative Effectiveness of Bbiologic or Small Molecule Therapies in IBD</td>
<td>Crohn's and Colitis Foundation</td>
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<td>Multi-component Implementation of SDM for Uterine Fibroids Across Socioeconomic Strata</td>
<td>Trustees of Dartmouth College</td>
<td>Glyn Elwyn</td>
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<td>Tailored Implementation of a Decision Support Strategy for Left Ventricular Assist Devices across All Programs in the United States</td>
<td>University of Colorado Denver</td>
<td>Dan Matlock</td>
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<td>Using PCORI Data to Drive Better Decisional Quality for Men with Localized Prostate Cancer</td>
<td>The Regents of the University of California</td>
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<td>Comparative Effectiveness Randomized Trial to Improve Stroke Care Delivery: C3FIT: Coordinated, Collaborative, Comprehensive, Family-based, Integrated, and Technology-enabled Care</td>
<td>Vanderbilt University Medical Center</td>
<td>Kenneth Gaines</td>
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<td>CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer</td>
<td>University of Washington</td>
<td>John Gore</td>
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<td>Remote Cognitive Behavior Therapy for Major Depression (RTD) in Primary Care</td>
<td>West Virginia University</td>
<td>Robert Bossarte</td>
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<td>Preventing Tipping Points in High Comorbidity Patients: A Lifeline from Health Coaches</td>
<td>Clinical Directors Network, Inc.</td>
<td>Jonathan Tobin</td>
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<td>System-Level Capture of Family History Data to Assess Risk of Cancer and Provide Longitudinal Care Coordination</td>
<td>Kaiser Permanente Division of Research</td>
<td>Douglas Corley</td>
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<td>Primary Care and Community-Based Prevention of Mental Disorders in Adolescents</td>
<td>The Board of Trustees of the University of Illinois</td>
<td>Benjamin Van Voorhees</td>
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<td>Specialty Medical Homes to Improve Outcomes for Patients with Inflammatory Bowel Disease (IBD) and Behavioral Health Conditions</td>
<td>UPMC Center for High-Value Health Care</td>
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<td>Transseptal versus Retrograde Aortic Approach to Left Ventricular Catheter Ablation</td>
<td>University of California, San Francisco</td>
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<td>Comparative Effectiveness of Metformin for Type 2 Diabetes with Chronic Kidney Disease</td>
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<td>A Randomized Trial to Promote Informed Decisions about Cancer Screening in Older Adults (PRIMED Study)</td>
<td>Massachusetts General Hospital</td>
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<td>Patient and Caregiver-Centered Diabetes Telemanagement Program for Hispanic/Latino Patients</td>
<td>Northwell Health</td>
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<td>Dissemination and Implementation of Effective Childhood Obesity Treatment Innovations</td>
<td>Massachusetts General Hospital</td>
<td>Elsie Taveras</td>
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<td>Effectiveness of Universal versus Targeted School Screening for Adolescent Major Depressive Disorder</td>
<td>Penn State College of Medicine</td>
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<td>Disseminating and Implementing Patient and Family Centered I-PASS to Improve Patient Safety</td>
<td>The Children's Hospital Corporation</td>
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<td>Improving CER\PCOR Methods for Analyzing Linked Data Sources in the Absence of Unique Identifiers</td>
<td>Brown University</td>
<td>Roee Gutman</td>
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<td>Enhancing Hybrid Study Designs for Comparative Effectiveness Research</td>
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<td>Bayesian Modeling Framework for Causal Inference and Assessing Sensitivity to Unmeasured Confounding with Multiple Treatments</td>
<td>Department of Health Evidence and Policy, Icahn School of Medicine at Mount Sinai</td>
<td>Liangyuan Hu</td>
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</table>
OUR MISSION

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.

OUR VISION

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

"Leave your footprint in the sand by getting involved in research and education programs, I tell people. Research may not save your life, but it may save your grandchild’s life or your great-grandchild’s life."

Freddie White-Johnson, MPPA
Founder and President, Fannie Lou Hamer Cancer Foundation; PCORI Advisory Panel Member; Joint Project Lead for Eugene Washington PCORI Engagement Award