OVERVIEW
PCORI was created as part of the Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010. The agency is charged with providing a better understanding of prevention, diagnosis and treatment options for patients, their caregivers, health care providers and other stakeholders. This charge is met through 1) research, 2) an emphasis on research methodology and 3) efforts to encourage other funding agencies to incorporate patient-centered research methods. PCORI is supported through the Patient-Centered Outcomes Research Trust Fund, combining federal and fee-based revenue for agency operation through September 30, 2019.

Specific Interests
Patient-centered is not just in this agency’s name; it drives their every action. PCORI talks about a “movement that meaningfully involves patients and incorporates their voice” (PCORI 2012 Annual Report, p.2) throughout the process with an ultimate goal of influencing health care for the betterment of patients. PCORI’s National Research Priorities, along with current budget percentages, are:
1. Assessment of Prevention, Diagnosis and Treatment Options (40%)
2. Improving Healthcare Systems (20%)
3. Communication/Dissemination Research (10%)
4. Addressing Disparities (10%)
5. Accelerating Patient Centered Outcomes Research and Methodological Research (20%)

Approach
PCORI refers to their approach as “research done differently” (PCORI 2012 Annual Report, p. 4), starting with establishment of strict methodology standards for patient centered outcomes research. Their Engagement Program involves patients, caregivers, healthcare industry leaders, healthcare advocates and other stakeholders in all aspects of PCORI’s operation. These groups participate in the planning stages, as key participants on research teams and within the research contract merit review process.

AGENCY ORGANIZATION
PCORI is a 501(c)(1) non-profit corporation, not a federal agency. It is governed by a 21-member Board of Governors, drawn from academia, the health care industry, corporations outside of healthcare and non-profits, as well as the Directors of the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRO). The Methodology Committee’s role is to identify best practice patient-centered research methods and to ensure these methods are employed in all research supported by PCORI. Committee members are experts in science, medicine, epidemiology, health care technology and the health care industry. Both the Board and the Committee are appointed by the US Comptroller General.

RESEARCH CONTRACTS PROGRAM
PCORI promotes their research contracts program through PCORI Funding Announcements (PFAs), characterized as broad and targeted PFAs. Broad PFAs solicit investigator-initiated projects addressing one or more of PCORI’s National Research Priorities. Targeted PFAs focus on specific topics prioritized by patients and other healthcare stakeholders. PCORI recently moved from 3 annual funding cycles to 4. For 2014, applications responding to broad PFAs will be considered in May and November; applications responding to targeted PFAs will be submitted for the February and August deadlines. Project funding ranges from $500,000 to several million dollars across 3-5 years project periods; indirect costs are limited to 40%. Universities and colleges, private and public sector research organizations, non-profits, for-profits, hospitals, labs, manufacturers and local/state/federal government agencies are eligible applicants.

Awards/Success Rates
As of February, 2014, PCORI has funded 192 research studies totaling over $316 million. Plans call for spending an additional $1.5 billion over the next 3 years (Source: “PCORI at 3 Years – Progress, Lessons and Plans”, J. Selby and S. Lipstein, New England Journal of Medicine2014: 370: 592-595, February 13, 2014). PCORI’s first funding cycle resulted in a 5% funding rate; the second cycle (Spring, 2013) yielded a 12% funding rate. Joe Selby,
PCORI Director, indicated he sees the upward trend as evidence that proposers are better understanding PCORI’s expectations in terms of rigorous patient-centered outcomes research methodology and patient/caregiver involvement (Source: PCORI Blog, July 22, 2013).

Additional Funding Mechanisms:
To better round out the agency’s research funding portfolio, PCORI recently introduced a new initiative titled “Pragmatic Clinical Studies and Large Simple Trials” with budgets up to $10 million in direct costs.

Contact with PCORI Program Staff:
PCORI encourages principal investigators (PIs) to contact program officers with questions and help in determining if research projects are applicable and responsive to PCORI needs via e-mail or telephone. PCORI personnel are also available for online proposal submission questions.

Typical PCORI Proposal Process:
1) PI determines suitability of proposed project to PCORI mission and National Research Priorities
2) PI contacts program officer for assistance and questions about application
3) PI submits required letter of intent (LOI). For broad PFAs, the LOI is used to gauge the number of applications expected. For targeted PFAs, PCORI reviews for content and relevance and invites full applications from some PI’s.
4) The application is submitted through the PCORI online system
5) The application goes through merit review
6) Highest scoring applications go through financial review by procurement specialists
7) PCORI senior management committee reviews applications based on combined technical and cost scores for “best value”
8) A verbal offer is made to the PI, followed by Best and Final negotiations
9) A research contract is executed

Application Review Process:
Scientists, patients, clinicians, patient advocates, caregivers and other healthcare stakeholders are all actively involved in the PCORI review process. Each reviewer’s score is equally weighted to insure that all views are represented in final funding decisions. PCORI uses a 9-point scoring system with 9 being the lowest rank. General review criteria are impact of the condition in terms of individual and population health, potential for improved care/outcomes, technical merit, patient-centeredness and patient/stakeholder engagement. The highest ranking applications are then given cost scores by procurement specialists. A senior management committee makes final funding decisions based on both merit and cost scores. PCORI announces funding decisions via live Board of Governors’ webinars, followed up by verbal notification, negotiation and contract execution.

What Happens Next?
Once research contracts are in place, PIs begin work on their projects. Those not selected for funding receive notice and can elect to go through a formal debriefing with agency personnel. PCORI has no resubmission limits so unfunded applicants should take advantage of the debriefing process and start planning their reworked applications in anticipation of the next round of funding.