Centering on PCORI: General guidelines, application and resources

Washington University
Institute of Clinical & Translational Sciences

PCORI grant workshop Mar 4, 2014
Presenter: Dr. Elizabeth (Betsy) Keath
ICTS Project Manager and Navigator for Translational Research
Did you know?

• PCORI ‘top 5’
  – An independent, non-profit organization authorized by Congress in 2010 as part of the Patient Protection and Affordable Care Act
  – Over $316 million committed through 2013 on 189 national priority projects
  – Plan to commit as much as $1.5 billion in research projects over the next 3 years
  – An institute nearly named ‘CCERI’, as the Comparative Clinical Effectiveness Research Institute
  – Motto: “Research done differently”
Patient-centered outcomes Research

- Actively engages patients and key stakeholders throughout the research process.
- Compares important clinical management options.
- Evaluates the outcomes that are most important to patients.
- Addresses implementation of the research findings in clinical care environments.

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options that balance patient questions about their own:

- Expectations
- Options
- Outcomes
- Decisions
Patient Centered Outcomes

PCO are outcomes that **directly** impact patient’s lives and well being in their cultural community context.

Qualifiers for PCO for PCORI funding include:

- Meaningful effect size
- Ability to evaluate the heterogeneity of treatment effects
- Rooted in real-world settings

Biomarkers
Cost effectiveness analysis
Cost of coverage decisions

Special features of PCORI awards mark significant differences from other agencies

- “contract” vs “grant”: PCORI focus on meeting milestones, demonstrating accountability
- Patient & Stakeholder Engagement Plan: engage early and continuously
- Reproducible and Transparent Research Plan: concise and robust study design; focus on patient intervention group
- D & I Assessment: highlight generalizability and know your deliverables!
- PCORI Criteria Outlined by Statute
- Methodology Standards & Compliance: CER requires two (experimental & control) patient groups

Institute of Clinical and Translational Sciences
Washington University in St. Louis
National PCORI Research Priorities

- Comparisons of alternative clinical options; identifying patient differences in response to therapy; preferences for various outcomes
- Improving system support of patient self-management; coordination of care (complex conditions)
- Understand differences in effectiveness and preferences across groups; reducing disparities though PCOR findings
- Understanding and enhancing shared decision-making; alternative strategies for dissemination; patient health literacy studies
- Improving study designs and analytic methods of PCOR; building and improving shared data networks
PCORI’s First Targeted Research Topics

Stakeholder-vetted research topics identified with specific PFA calls

<table>
<thead>
<tr>
<th>Topic</th>
<th>Population</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment options for uterus fibroids</td>
<td>Women age 30-50 years</td>
<td>Most common gynecological condition</td>
</tr>
<tr>
<td>Safety/benefits for treatment options for severe asthma</td>
<td>Multiple Populations</td>
<td>Affects almost 20 million Americans</td>
</tr>
<tr>
<td>Fall prevention in the elderly</td>
<td>Elderly</td>
<td>Leading cause of fatal and nonfatal injuries among those 65 and older</td>
</tr>
</tbody>
</table>
**Eugene Washington PCORI Engagement Awards**

The Pipeline to Proposal awards are an early effort under PCORI’s new [Eugene Washington PCORI Engagement Awards program](#), which will encourage community engagement in patient-centered outcomes research (PCOR) by supporting projects to enhance knowledge of PCOR, training in partnership development and devising research proposals; and efforts to get research results adopted in clinical practice.

**GOALS**

- Develop PCOR community; establish infrastructure
  => **KNOWLEDGE AWARDS**
- Engage the community in research process; establish trust/legitimacy
  => **TRAINING & DEVELOPMENT AWARDS**
- Promote dissemination and implementation; encourage adoption of PCOR findings
  => **DISSEMINATION AWARDS**

PCORI approved 30 projects totaling more than $400,000 under the pilot phase of its "Pipeline to Proposal" awards program. These Tier I awards were initially offered in the Western US to build communities around common health research interests. The program will soon be expanded nationwide.
PCORI New Funding Cycles

<table>
<thead>
<tr>
<th>FUNDING CYCLE</th>
<th>APPLICATION DEADLINE Approx.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Winter</td>
<td>Late Jan/Early Feb</td>
</tr>
<tr>
<td>Spring*</td>
<td>May</td>
</tr>
<tr>
<td>Summer</td>
<td>August</td>
</tr>
<tr>
<td>Fall*</td>
<td>Nov</td>
</tr>
</tbody>
</table>

Additional changes:

- Five broad priority PFAs accepted only during Spring and Fall cycles (*).
- Targeted calls and applications submitted during Winter and Summer cycles. Some PFAs will accept applications only after preliminary review of LOI.
- Elimination of restriction on resubmitted proposals regarding timing and frequency.
  - Consideration of critiques essential!
  - Last round, resubmitted grants were half the total of awarded projects funded!
- Updated application process.
- More aggressive review timetable.
Application Resources at PCORI

• Sign up for the flow of PCORI updates
   http://www.pcori.org/home/signup/

• Explore the PCORI 101 video
   http://www.pcori.org/news-room/videos/

• LOI submission – users manual is available
   http://www.pcori.org/assets/2013/10/PCORI-Online-Start-a-LOI.pdf

• Full proposal submission – users manual is available
   http://www.pcori.org/assets/2013/10/PCORI-Online-Submitting-an-Application.pdf
Application Resources at PCORI

• Separate guidelines established for PFAs 1-4 and 5 (Improving PCOR Methods)
  http://www.pcori.org/assets/2014/02/PCORI-PFA-2014-Spring-Application-Guidelines.pdf and for methods,

• Examine real-world sample engagement plans

• Check out streamlined instructions and new application checklist
ICTS: Proposal Development/Application Resources

- **CORES**
  - RDBG: Research Design and Biostatistics Group
  - DIRC: Dissemination and Implementation Research Core
ICTS: Proposal Development/Application Resources

• **CORES**
  – CCER: Center for Community Engaged Research
  – CCRE: Center for Clinical Research Ethics

The Center for Community-Engaged Research (CCER) is a transformative initiative that fosters collaborative research partnerships between and among the community at large, community organizations, ICTS academic institutions, community-based health providers, and community researchers. Dynamic and productive, the CCER is a platform to establish partnerships between academic and community researchers.

The Center for Clinical Research Ethics (CCRE):

- Helps ensure that all ICTS trainees receive training in clinical research ethics (CRE) and the responsible conduct of research (RCR) that exceeds the minimum standards set by NIH;
- Conducts and supports collaborative research on clinical research ethics, research integrity, and the intersection of ethics and community engagement; and
- Shares expertise in research ethics with individuals, policy committees, and others through consulting activities.
ICTS: Proposal Development/Application Resources

• **PEOPLE**
  
  – Aspiring applicants & funded investigators
  
  – Reviewers
    * Review panels for Priority PFAs
    * Review panel for Targeted Research Topics
  
  – Navigation to Resources
    o Electronic eNavigator tool
    o Personal consultation

<table>
<thead>
<tr>
<th>Investigator</th>
<th>PFA</th>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tessa Madden</td>
<td>Comm. and Dissem. Research</td>
<td>Implementation of Patient-Centered Contraceptive Provision in Community Settings</td>
</tr>
<tr>
<td>Kaharu Sumino</td>
<td>Asthma treatment options in URM</td>
<td>Preference and Effectiveness of Symptom-Based Adjustment of Inhaled Corticosteroid Therapy in African American Children</td>
</tr>
<tr>
<td>Feliciano (Pele) Yu – WU lead Chris Forrest (CH-Philadelphia) PI</td>
<td>Clin. Data Research Network PCORNNet</td>
<td>A National Pediatric Learning Health System (PedsNet)</td>
</tr>
</tbody>
</table>
ICTS: Proposal Development/Application Resources

• TEMPLATES AND TOOLS
  – Access to specialized conferences

Comparative Effectiveness Research Center

2014 Symposium

Washington University 2014 CER Symposium

Date: April 16, 2014
Time: 8:00 am - 3:00 pm
Location: Eric P. Newman Education Center (EPNEC) here at Washington University
Theme: "Methods in Patient Centered Outcomes Research (PCOR) and Comparative Effectiveness Research (CER)"
ICTS: Proposal Development/Application Resources

• **TEMPLATES AND TOOLS**
  – Guides/manuals from CTSAs (CTSI at UCSF; [http://accelerate.ucsf.edu/community/working-with-researchers](http://accelerate.ucsf.edu/community/working-with-researchers))
ICTS: Proposal Development/Application Resources

• **TEMPLATES AND TOOLS**
  
  
  – Community partner designated portion on ICTS website ([http://www.icts.wustl.edu/community-partners](http://www.icts.wustl.edu/community-partners))
  
ICTS: Proposal Development/Application Resources

• **TEMPLATES AND TOOLS**
  – ICTS News spotlights
  – ICTS writing tools
    (http://www.icts.wustl.edu/icts-researchers/tools-resources/tools-and-resources-for/academic-researchers)

Researchers, Community Partner to Promote Community Health
Melody Goodman, PhD, assistant professor in WU School of Medicine's Division of Public Health Services, established a program to educate community members about research. See articles in the St. Louis Post-Dispatch or Washington University Record for additional information about this innovative program.

PCORI Application Checklist
Using the PCORI review criteria and with input from ICTS members who have served in the PCORI review process, a grant writing tool checklist has been developed.
Summary

- Understand PCORI and stay updated! [www.pcori.org](http://www.pcori.org)
- Visit ICTS website: [http://icts.wustl.edu](http://icts.wustl.edu)
  - Become a member – *it takes 5 minutes!*
  - Explore the ICTS Honeycomb to find Core services for every phase of your clinical and translational research project in PCOR
- Contact ICTS Project Manager/Navigator
  [ICTSNavigator@wustl.edu](mailto:ICTSNavigator@wustl.edu)
- Cite the grant when using Core services

Supported by the Clinical and Translational Science Award *(CTSA)* program of the NIH National Center for Advancing Translational Sciences *(NCATS)* at the National Institutes of Health *(NIH)*

**Grant Numbers UL1 TR000448, KL2 TR000450, TL1 TR000449**