Welcome and Overview

Gray Norquist, Brigette Scott, and Scott Solomon
Contracts Management and Administration

June 22, 2015

Welcome!

Brigette Scott, MA
Communications Manager,
Contracts Management and Administration
Housekeeping – Things You Need to Know!

- PCORI Staff
- Restrooms

Morning Recharge: 9:45 am – 10:00 am
Midday Nourishment: 12:00 pm – 1:30 pm
Afternoon Recharge: 3:30 pm – 3:45 pm
OMG – I Need to Check My Email!
Workshop Access Code

pcori2015
Mobile Site and Presentations

- Atlanta PCORI Workshop Mobile Site URL: [http://goo.gl/OwKHGI](http://goo.gl/OwKHGI)

Connect with Us!

- Email: [contractsworkshop@pcori.org](mailto:contractsworkshop@pcori.org)
- Twitter: [#PCORI](https://go.to/JhzuXA)
You Are Here!

Breakout Sessions

General Sessions - 10th Floor

Breakfast and Lunch

Questions: Help Desk!

- Accessing/creating your account in the PCORI Online system
- Updating your application
- Finding your institution
- Assigning your Administrative Official
- Understanding PCORI Funding Announcement (PFA) requirements
- Submitting your budget
- Reporting and compliance
- Notifications about the status of your application and funding decisions
- General pre- and post-award processes
Welcome!

Scott Solomon
Director of Contracts
Management and Administration

Session Objectives
• Discuss PCORI’s history, mission, and vision
• Brief overview of PCORI’s research portfolio and unique approach to funding research
• Describe the reason for this workshop
About Us

• An independent research institute authorized by Congress in 2010; governed by a 21-member Board representing the entire healthcare community
• Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
• Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns

Why PCORI?

• Research has not answered many questions patients face
• People want to know which treatment is right for them
• Patients need information they can understand and use
PCORI Has a Broad and Complex Mandate

“assist patients, clinicians, purchasers, and policy-makers in making informed health decisions...through research and evidence synthesis...and the dissemination of research findings”
—from PCORI’s authorizing legislation

PCORI Has a Broad and Complex Mandate

PCORI’s 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 Focus

Comparative Clinical Effectiveness Research

- Patient-centered
- Answering questions that matter to patients and other clinical decision makers
- Comparisons of outcomes that matter to patients

Strategic Goals

Increase Quantity, Quality, and Timeliness of Research Information

Speed the Implementation and Use of Evidence

Influence Research Funded by Others
PCORI’s Organizational Structure

Government Accountability Office (GAO)

Board of Governors (BoG)

Methodology Committee (MC)

Chief Science Officer

Chief Engagement & Dissemination Officer

Chief Operating Officer

Executive Director

CMA’s Organizational Structure

Contracts Management & Administration (CMA)

Pre-Award

Post-Award

Contracts Communications

Contracts Systems
Our National Priorities for Research

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication & Dissemination Research
- Addressing Disparities
- CER Methods and Infrastructure

Our Program Directors

- David Hickam, MD, MPH: Assessment of Prevention, Diagnosis, and Treatment Options
- Steven Clauser, PhD, MPA: Improving Healthcare Systems
- Jean R. Slutsky, PA, MSPH: Communication & Dissemination Research
- Romana Hasnain-Wynia, MS, PhD: Addressing Disparities
- Rachael Fleurence, PhD: CER Methods and Infrastructure
Key Features of PCORI Research

Our work answers patients’ questions:

“Given my personal characteristics, conditions, and preferences...

...what should I expect will happen to me?”

...what are my options and what are the potential benefits and harms of those options?”

...what can I do to improve the outcomes that are most important to me?”

...how can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

PCORI Emphasizes Engagement for Getting to Practical, Useful Research

We engage stakeholders at every step:

Generating and Prioritizing Research Questions

- Advise Us on What To Study

Reviewing and Conducting Research

- Review Proposals and Partner in Research

Portfolio Review

- Tell Us How We’re Doing

Dissemination and Implementation

- Help Us Share the Findings
**Session Objectives**

- Discuss PCORI’s history, mission, and vision
- Brief overview of PCORI’s research portfolio and unique approach to funding research
- Describe the reason for this workshop

---

**Research And Results**

**What We’ve Funded**

- **400** Research Projects Approved
- **$868.6** MILLION in Research Funds Awarded
- **39** STATES with Research Funded

---

Our GROWING RESEARCH PORTFOLIO

http://www.pcori.org/research-results
Funded Projects to Date

Total number of research projects awarded: **400**

Total funds awarded: **$868.6 million**

Number of states where we are funding research: **39 states** (plus the District of Columbia, Quebec, and Puerto Rico)

---

Snapshot of Funded Projects

<table>
<thead>
<tr>
<th>MEDICAL CONDITION</th>
<th>NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>38</td>
</tr>
<tr>
<td>Mental/Behavioral Health</td>
<td>38</td>
</tr>
<tr>
<td>Cardiovascular Health</td>
<td>22</td>
</tr>
<tr>
<td>Neurological Disorders</td>
<td>18</td>
</tr>
<tr>
<td>Nutritional and Metabolic Disorders</td>
<td>17</td>
</tr>
<tr>
<td>Rare Disease</td>
<td>17</td>
</tr>
<tr>
<td>Respiratory Diseases</td>
<td>17</td>
</tr>
<tr>
<td>Multiple/Co-Morbid Chronic Conditions</td>
<td>16</td>
</tr>
<tr>
<td>Trauma/Injury</td>
<td>12</td>
</tr>
<tr>
<td>Reproductive and Perinatal Health</td>
<td>11</td>
</tr>
<tr>
<td>Muscular and Skeletal Disorders</td>
<td>9</td>
</tr>
<tr>
<td>Kidney Disease</td>
<td>7</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>5</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>3</td>
</tr>
<tr>
<td>Digestive System Diseases</td>
<td>2</td>
</tr>
<tr>
<td>Allergies and Immune Disorders</td>
<td>1</td>
</tr>
<tr>
<td>Skin Disease</td>
<td>1</td>
</tr>
<tr>
<td>Other/Non-Disease Specific</td>
<td>20</td>
</tr>
</tbody>
</table>
PCORI’s Past Funding Lines

Current Funding Commitments
LOIs, Applications, and Awards

- **Letters of Intent Received**: 31
- **Applications Invited**: 228
- **Submitted Applications**: 79
- **Identified for Funding**: 150

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addressing Disparities</td>
<td>150</td>
<td>30%</td>
</tr>
<tr>
<td>Assessment of Prevention, Diagnosis, and Treatment Options</td>
<td>228</td>
<td>45%</td>
</tr>
<tr>
<td>Communication &amp; Dissemination Research</td>
<td>122</td>
<td>24%</td>
</tr>
<tr>
<td>Improving Healthcare Systems</td>
<td>76</td>
<td>15%</td>
</tr>
<tr>
<td>Improving Methods for PCOR</td>
<td>121</td>
<td>24%</td>
</tr>
<tr>
<td>Clinical Pragmatic Studies</td>
<td>169</td>
<td>33%</td>
</tr>
</tbody>
</table>

**Awardees**
- **84 Awardees (17%)** of total
- **60 Awardees (12%)** of total
- **120 Awardees (24%)** of total
- **120 Awardees (24%)** of total
- **1 Other Awardee (<1%)** of total

---

Funding by Geographic Distribution

- **West**: 96 Awardees (24% of total)
- **Midwest**: 65 Awardees (16% of total)
- **South**: 120 Awardees (30% of total)
- **Northeast**: 120 Awardees (30% of total)
- **1 Other Awardee (<1%)** of total
Comparison of Funding Level Announced with Funding Level Awarded

Time from Award to Contract Execution
Fixed-Price Contracts

**Pilot Expenditures**

- Expected
- Actual

<table>
<thead>
<tr>
<th>Period</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fixed-Price Contracts

**Cycle I Expenditures**

- Expected
- Actual

<table>
<thead>
<tr>
<th>Period</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cost-Reimbursable Contracts

Why Are Awards at PCORI Different?

- PCORI research contracting process
  - What is the difference between a research contract and a research grant?
- The authorizing law
  - How it affects PCORI research projects
Types of Federal Funding Mechanisms

- Grants
- Cooperative Agreements
- Contracts

Why Does PCORI Issue Contracts?

- Helps PCORI Meet Legislative Expectations
- Ensures Accountability
- Supports Establishment and
PCORI’s Authorizing Law: Formation

• PCORI is an independent non-profit authorized by federal law with funding established by federal law
  — PCORI is NOT a federal agency or a federal contractor or grantee
  — Funding is from the PCOR Trust Fund and other federal sources
  — PCORI cannot accept donations or generate revenue

Contract Provisions Relating to PCORI’s Authorizing Law

Contracts reflect PCORI’s authorizing law
• Adherence to PCORI Methodology Standards
• Consultation with the PCORI Advisory Panels on Clinical Trials and Rare Diseases
• Peer Review of Primary Research
• Making Research Findings Publicly Available
• Conflicts of Interest
• Notifications About Publications
• Indemnification & Insurance
• Intellectual Property Rights in PCORI-Funded Research
• Contract Governing Law
• Data Sharing Plans
Session Objectives

- Discuss PCORI’s history, mission, and vision
- Brief overview of PCORI’s research portfolio and unique approach to funding research
- Describe the reason for this workshop

What We Want To Accomplish

Help you improve:

- Application Quality
- Contract Negotiations
- Award Performance by avoiding:
  - Unrealistic milestones
  - Inability to recruit study subjects
  - Inability to control and manage subcontractors
More Reasons for Our Workshop—Administrative Non-Compliance

Applications

- Over Budget/Project Period
- Over Page Limit
- Missing Required Documents
- Administratively Compliant

Programmatic Non-Compliance

<table>
<thead>
<tr>
<th>PFA</th>
<th>Spring 2014 LPS</th>
<th>Fall 2014</th>
<th>Winter 2015</th>
<th>Spring 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD</td>
<td>--</td>
<td>22.7%</td>
<td>--</td>
<td>26.1%</td>
</tr>
<tr>
<td>CDR</td>
<td>--</td>
<td>18.0%</td>
<td>--</td>
<td>24.1%</td>
</tr>
<tr>
<td>CER</td>
<td>--</td>
<td>34.5%</td>
<td>--</td>
<td>45.3%</td>
</tr>
<tr>
<td>IHS</td>
<td>--</td>
<td>36.0%</td>
<td>--</td>
<td>54.9%</td>
</tr>
<tr>
<td>Methods</td>
<td>--</td>
<td>65.3%</td>
<td>--</td>
<td>66.3%</td>
</tr>
<tr>
<td>Broads Total</td>
<td>--</td>
<td>34.8%</td>
<td>--</td>
<td>46.8%</td>
</tr>
<tr>
<td>LPS</td>
<td>20.1%</td>
<td>14.2%*</td>
<td>24.2%**</td>
<td>--</td>
</tr>
</tbody>
</table>
Past CMA PCORI Workshops

- Washington, DC (July, 2014)
- San Diego, CA (September, 2014)
- Houston, TX (February, 2015)
- Atlanta, GA (June, 2015)
  - Improvements to this workshop include:
    - Breakout Sessions directed at specific roles
    - A Pragmatic Studies track
    - More time and staff available for one-on-one sessions

Where are You From?

- Atlanta Workshop 2015 attendees represent 33 states and Puerto Rico
- Attendees from states without current PCORI awards: Mississippi, New Jersey, Delaware, and West Virginia
- In less than one year, 593 PIs and Research Administrators have attended a CMA Workshop
**Significant Workshop Statistics**

- **Organizations**:
  - Drafted LOIs: 1980
  - Full Application: 262
  - LOIs Submitted: 892
  - In-Person Review: 34
  - Applications Funded: 792

- **Attendees**:
  - Full Application: 259
  - LOIs Submitted: 689
  - In-Person Review: 134
  - Applications Funded: 132
  - Talked: 18

---

**The Workshop Opportunity**

Talk with us!
The Journey From Application to Closeout

Questions?
Thank You!

Scott Solomon
Director of Contracts Management and Administration