

Board of Governors Meeting via Teleconference/Webinar

June 19, 2018

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer



Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:05	Consider for Approval: Minutes of the May 22, 2018 Board Meeting
12:05–12:25	Consider for Approval: Update of PCORI Governing Documents
12:25-12:55	Consider for Approval: Proposed Slate for Cycle 2 2017 Shared Decision Making Approaches in Practice Settings PFA
12:55-1:10	FY2018 Mid-Year Financial Review
1:10	Wrap up and adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the May 22, 2018 Board Meeting

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Update of PCORI's Governing Documents

Kerry Barnett, JD

Chair, Governance Committee; Board Vice Chairperson

Mary Hennessey, Esq.

General Counsel



Update of PCORI Governing Documents

- Charters for PCORI's Committees and Advisory Panels call for an annual or periodic review to be conducted. Changes to most Committee and Advisory Panel charters require Board approval
- Each year, Committees review their respective charter and the charters of the Advisory Panel(s) whose activities are overseen by the Committee(s)
- The Governance Committee reviews Committee charters to address overall governance matters, including for governance consistency and alignment with DC nonprofit law. This year, the Governance Committee also reviewed PCORI's Bylaws



Update of PCORI Governing Documents

- As a result of the Committee reviews, the Board is asked to consider approving the following amended PCORI governance documents:
 - PCORI Bylaws
 - Charters for the following Committees:
 - Methodology Committee (MC)
 - Strategy Committees: EDIC, RTC, SOC
 - Selection Committees (SC)
 - Finance and Administration Committee (FAC)
 - Executive Committee
 - Governance Committee
 - Charters for the following Advisory Panels:
 - Healthcare Delivery and Disparities Research (HDDR) Advisory Panel
 - Clinical Effectiveness and Decision Science (CEDS) Advisory Panel
- The Board is asked to sunset the Scientific Publications Committee Charter and dissolve the Scientific Publications Committee



Governance-related Proposed Revisions to Bylaws and Committee Charters

- Governance Committee recommends updated governance-related language to the Bylaws and Committee Charters, including to clarify:
 - **GAO's Appointment of Board Members:** GAO appoints Board members for a 6-year term and does not appoint a new Board member for the remainder of the term of a Board member who prematurely leaves the Board
 - **GAO's Appointment of Methodology Committee Members:** Consistent with PCORI's authorizing law, GAO appoints "not more than 15" MC members (in addition to NIH and AHRQ Directors/designees) and MC members do not have specific terms or term limits. Language is removed that references terms, term limits, and staggered terms
 - **Quorum requirements:** Quorum requirements are determined by the number of members of the Board/Committee actually appointed, not by the number of seats
 - **Authority of Committees:** Revised language recognizes different ways the Board can grant authority to Committees and ties language that restricts the power of Committees to the terminology used in the DC nonprofit law



Highlights of Other Proposed Revisions to Committee Charters

- **Engagement, Dissemination, and Implementation Committee:** Add oversight responsibilities over scientific publishing strategy given recommendation to sunset the Scientific Publications Committee
- **Research Transformation Committee:** Add oversight responsibilities over sustainability planning for PCORnet given evolution of PCORnet
- **Governance Committee:** Clarify eligibility for membership and confirm that Committee can consult with GAO on Board reappointments as well as new appointments
- **Selection Committees:** Specify a maximum number of Methodology Committee members that can be appointed given that a maximum number of Board members is specified. Retain language confirming that Board members must be a majority



Highlights of Proposed Revisions to Advisory Panel Charters

- The respective overseeing Committees are recommending revisions to the following Advisory Panel Charters:
 - **Advisory Panel on Healthcare Delivery and Disparities Research (HDDR)**
 - Provide for co-chair leadership on Advisory Panel
 - **Advisory Panel on Clinical Effectiveness and Decision Science (CEDS)**
 - Reflect opportunities to make recommendations on stakeholder groups that may have an interest in dissemination and implementation efforts



Proposed Motion

- That the PCORI Board of Governors approve each of the following:
 - Adoption of the following proposed governing documents:
 - Amended PCORI Bylaws
 - Revised Charters for the following Committees:
 - Methodology Committee (MC)
 - Strategy Committees:
 - » Engagement, Dissemination and Implementation Committee (EDIC)
 - » Research Transformation Committee (RTC)
 - » Science Oversight Committee (SOC)
 - Selection Committees (SC)
 - Finance and Administration Committee (FAC)
 - Executive Committee
 - Governance Committee
 - Revised Charters for the following Advisory Panels:
 - » Healthcare Delivery and Disparities Research (HDDR) and Clinical Effectiveness and Decision Science (CEDs)
 - Sunset of the Scientific Publications Committee Charter and dissolution of the Scientific Publications Committee



Board Vote

Call for a Motion to:

- **Approve** the Proposed Motion

Call for the Motion
to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



Proposed Funding Slate from the PCORI Funding Announcement (Cycle 2 2017):

Implementation of Effective Shared Decision Making Approaches in Practice Settings (SDM PFA)

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination, and Implementation Committee (EDIC)

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer



Cycle 2 2017 – Shared Decision Making

Objective of the PFA

- To promote the targeted implementation and systematic uptake of shared decision making (SDM) in healthcare settings
- In line with PCORI goals of **supporting patients in making informed decisions** about their care, and of **promoting the use of evidence** for decisions
- PCORI definition of an SDM strategy:
 - An intervention or approach that draws on and presents available evidence to inform patients of available treatment options and their risks and benefits, and either engages patients in a decision-making process with their clinician that reflects their values, or promotes their ability to engage in such a process



Cycle 2 2017 – Shared Decision Making

Eligibility

- Projects must propose one of the following:
 - To implement a shared decision making (SDM) strategy that was formally tested and demonstrated to be effective in the context of a PCORI research award
 - An implementation project that will incorporate new PCORI CER evidence into an existing, tested shared decision making strategy, and then implement the updated shared decision making strategy in a practice setting
- Up to \$1.5M in direct costs (\$2.1M total costs) and up to 3 years in duration
- Funds available:
 - Up to \$6.5M per cycle, up to 2 cycles per year
 - (Only 1 cycle is proposed for FY 2018)



Cycle 2 2017 – Shared Decision Making

Merit Review Criteria

1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for dissemination
3. Technical merit (project design, outcomes, and evaluation)
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement



Cycle 2 2017 – Shared Decision Making

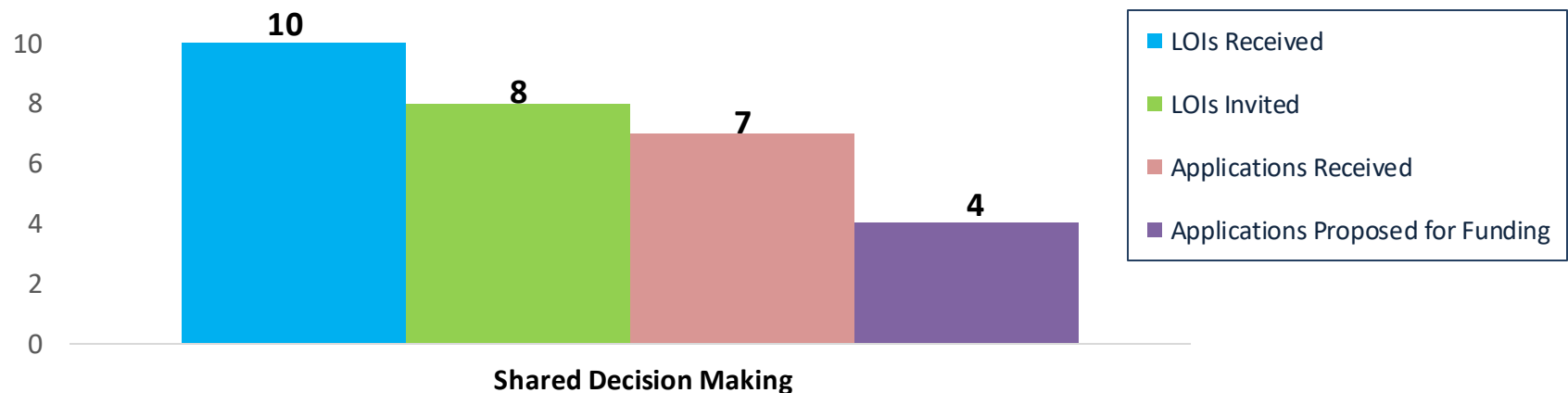
Process Overview

Application overview:

- 10 Letters of Intent (LOIs) submitted
- 8 LOIs invited to submit a full application - 80% of submitted LOIs
- 7 applications were received - 88% of invited LOIs

Overall funding rate is **57** percent

- We are proposing to fund 4 applications* out of 7 received applications



Cycle 2 2017 – Shared Decision Making

*4 Recommended Projects**

Project Title
Tailored implementation of a decision support strategy for left ventricular assist devices
Multi-component implementation of shared decision making for uterine fibroids across socioeconomic strata
Implementing individualized lupus patient decision-aid for immunosuppressive drugs
Using PCORI data to drive better decisional quality for men with localized prostate cancer

- Average requested budget per project is \$2M (total costs)

* All proposed projects, including requested budgets and project periods, are endorsed by the EDIC subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract



Cycle 2 2017 – Shared Decision Making

Project Overview

- Two of the four projects propose to implement an SDM strategy **formally tested and demonstrated to be effective in the context of a PCORI research award**
 - Tailored Implementation of a Decision Support Strategy for Left Ventricular Assist Devices
 - Implementing Individualized Lupus Patient Decision Aid for Immunosuppressive Drugs
- Two of the four projects propose to **incorporate new PCORI clinical comparative effectiveness research (CER) evidence into an existing and tested SDM strategy**, and then implement the updated strategy
 - Multi-Component Implementation of SDM for Uterine Fibroids across Socioeconomic Strata
 - Using PCORI Data to Drive Better Decisional Quality for Men with Localized Prostate Cancer



Cycle 2 2017 – Shared Decision Making

4 Recommended Projects

PFA	Amount Budgeted	Proposed Total Award*
Implementation of Effective Shared Decision Making Approaches in Practice Settings	\$6.5M	\$8.4M

Note: Budgeted amount is per cycle, up to 2 cycles per year. Only 1 cycle of funding is proposed for FY2018

**All proposed projects, including requested budgets and project periods, are endorsed by the EDIC subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract*



Board Vote

Call for a Motion to:

- **Approve** funding for the recommended slate of awards from the Cycle 2 2017 Implementation of Effective Shared Decision Making Approaches in Practice Settings PFA

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



FY2018 Mid-Year Financial Review (As of 3/31/2018)

Larry Becker

Chair, Finance and Administration Committee

Regina Yan, MA

Chief Operating Officer



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI Estimated Revenue and Expenditures

	In Millions	% of Total Expenditures
Revenue (thru FY2019)	\$ 3,349	
Program Services (thru FY2024)	3,013	90%
Awards	2,742	82%
<i>Actual, Inception to FY2017</i>	2,006	
<i>Planned, FY2018 to FY2021</i>	736	
Other Direct Program Costs	271	8%
Program Support (thru FY2024)	114	3%
Admin Support (thru FY2024)	222	7%
Total Expenditures (thru FY2024)	\$ 3,349	100%

Other Direct Program Costs are costs associated with the direct delivery of each program area. These costs may include personnel, professional services, and meeting & conferences associated with the Science, Research Infrastructure, Engagement, and Dissemination departments, as well as the Methodology Committee

Program Support are costs associated with supporting program delivery and evaluation across all program areas. These costs may include personnel, professional services, and meeting & conferences associated with the Evaluation & Analysis, Communications, and Program Support & Information Management departments

Admin Support are costs associated with general institutional support (such as the Board, administrative staff, rent, IT system infrastructure, human resources, finance, etc.)



PCORI FY2018 Revenue

(10/1/2017 – 3/31/2018)

REVENUE	<i>\$ in millions</i>
From PCOR Trust Fund	
Federal Appropriation	\$ 120.0
CMS Transfers from FHI/FSMI Trust Funds	115.5
PCOR Fee/True-Up	1.3
Interest	0.2
From Interest (U.S. Treasury Securities)	6.6
Total Revenue	\$ 243.6



PCORI Cash Balance and Outstanding Award Obligations

(as of 3/31/2018)

CASH BALANCE		<i>\$ in millions</i>
Cash -- PCOR Trust Fund	\$	15.7
Cash -- Operating Account		40.6
U.S. Treasury Securities		1,013.9
Total	\$	1,070.2

OUTSTANDING AWARD OBLIGATIONS		<i>\$ in millions</i>
Cumulative Funding Commitments*	\$	2,076.0
Outstanding Award Obligations**	\$	1,098.0

* Includes Research, Infrastructure, and Engagement, as well as Dissemination & Implementation funding commitments.

** Outstanding award obligations are amounts of contracts awarded that will require payments during a future period. These amounts will become due and payable as research progresses over time. We currently have projects that we will continue to make payments on through FY2024.



FY2018 Variance by Broad Categories

(As of 3/31/2018)

	FY2018 ANNUAL BUDGET	FY2018 YTD BUDGET (through 3/31/18)	FY2018 YTD ACTUAL (through 3/31/18)	FY2018 YTD VARIANCE (through 3/31/18)	
PROGRAM SERVICES	\$ 431,548,711	\$ 204,635,885	\$ 162,306,993	\$ 42,328,890	21%
PROGRAM SUPPORT	14,245,201	7,552,361	7,520,902	31,457	0%
ADMINISTRATIVE SUPPORT	32,833,522	16,688,848	14,151,872	2,536,977	15%
TOTAL	\$ 478,627,434	\$ 228,877,094	\$ 183,979,767	\$ 44,897,324	20%

- Of the \$44.9 million total underspent amount, \$36.3 million of the underspending is attributable to award payments, which is a timing variance. All award commitments are expected to be paid out as the research progresses over time.



FY2018 Expense Ratios by Broad Categories

(As of 3/31/2018)

	FY2018 YTD BUDGET (through 3/31/18)	% of Total Budget	FY2018 YTD ACTUAL (through 3/31/18)	% of Total Actual
PROGRAM SERVICES	\$ 204,635,885	89.4%	\$ 162,306,993	88.2%
PROGRAM SUPPORT	7,552,361	3.3%	7,520,902	4.1%
ADMINISTRATIVE SUPPORT	16,688,848	7.3%	14,151,872	7.7%
TOTAL	\$ 228,877,094	100%	\$ 183,979,767	100%



Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

