

Board of Governors Meeting

via Teleconference/Webinar

September 28, 2021
2:30 – 4:30 PM

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

2:30-2:35 **Welcome, Call to Order**

2:35-3:30 **Consider for Approval: Award Slates**

- *Addition to the Slate of Awards from the Cycle 3 2020 Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA*
- *Cycle 1 2021 Limited Competition Dissemination and Implementation PFA*
- *Cycle 1 2021 PCORnet®, The National Patient-Centered Clinical Research Network Phase 3*

3:30-3:45 **Consider for Approval: FY2022 Budget**

3:55-4:30 **Congressional Panel: Health Policy Landscape**

4:30 **Wrap up and Adjourn**

Overview of Award Slates to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Overview of Award Slates

Three award slates are under consideration for approval today:

PFA Type	Amount	PFA
Research	\$33M*	Cycle 3 2020 Phased Large Awards for Comparative Effectiveness Research (PLACER)
D&I	\$2M	Cycle 1 2021 Limited Competition D&I
Infrastructure	\$61M	Cycle 1 2021 PCORnet® Phase 3

Total **\$96M**

*An addition to the PLACER award slate previously approved by the Board in July (for \$135M)

FY2021 Funding Cycles in Context

PLACER Award Slates



This is our first cycle of PLACER and thus we have no historical data for comparison

Targeted PFAs	Historical Average	Cycle 3 2020 PLACER (Phased Large Awards)		Cycle 3 2021 PLACER (Phased Large Awards)	
LOIs Submitted	N/A	109		TBD	
LOIs Invited (% of LOIs Submitted)	N/A	60	55%	-	-
Applications Submitted (% of LOIs Invited)	N/A	52	87%	-	-
Applications Proposed for Funding (% of Applications Submitted)	N/A	5 + 1	10% (12%)	-	-

FY2021 Funding Cycles in Context

D&I Award Slates



LOI, Application, and Funding Rates for this cycle are similar to historical averages

Limited Competition (LC) D&I PFAs	Historical Average*	Cycle 3 2020 D&I LC PFA		Cycle 1 2021 D&I LC PFA		Cycle 2 2021 D&I LC PFA	
LOIs Submitted	11	6		6		8	
LOIs Invited (% of LOIs Submitted)	78%	4	67%	4	67%	4	50%
Applications Submitted (% of LOIs invited)	70%	3	75%	3	75%	4	100%
Applications Proposed for Funding (% of Applications Submitted)	33%	1	33%	1	33%		

* Historical Average based on experience from 2018-2020

FY2021 Funding Cycles in Context

PCORnet® Clinical Research Network (CRN) Award Slates



PCORnet® Clinical Research Network PFAs	Phase 1 Design 2013		Phase 2 Capacity Building 2015		Phase 3 Optimization* 2021	
LOIs Submitted	56		25		N/A	
LOIs Invited (% of LOIs Submitted)	31	55%	16	64%	N/A	N/A
Applications Submitted (% of LOIs invited)	28	90%	15	94%	9	100%
Applications Proposed for Funding (% of Applications Submitted)	11	40%	13	87%	8	89%
Total Funding	\$77M		\$111M		\$61M	

*For this Limited Competition PFA , PCORI solicited applications from Prime Organizations of CRNs currently funded to participate in PCORnet®

Today's Proposed Commitments in Context of FY2021 Commitment Plan



PFAs Funded in This Cycle	Commitment Target for FY2021	Cumulative FY2021 Commitments with addition of today's slates
Research, Cycle 3 2020: • Addition to PLACER Slate D&I, Cycle 1 2021: • Limited Competition Infrastructure, Cycle 1 2021: • PCORnet® Phase 3	\$482M*	\$495M**

*Target includes all funding categories and \$50M available for New Initiatives

**Cumulative commitments for all funding categories, including Engagement Awards and other small awards that do not come to the Board for approval

Note: No further commitments planned through the end of the fiscal year

Addition to the Cycle 3 2020 PLACER Award Slate

Barbara McNeil, Chair, MD, PhD

Chair, Selection Committee

Anne Trontell, MD, MPH

Associate Director, Clinical Effectiveness & Decision
Science

Project 1: Colonoscopy versus stool-based testing for older adults with a history of colon polyps



- **Research Question:** What is the comparative effectiveness of annual fecal immunochemical testing (FIT) vs colonoscopy for surveillance in older adults with a history of polyps?
- **Population & Setting:** Adults 70-82 years of age with a history of low-risk polyps due for colonoscopy at academic health centers, integrated delivery managed care systems, safety net health systems, and independent gastroenterology practices
- **Comparators:** FIT vs. colonoscopy
- **Outcomes of Interest:**
 - *Primary:* advanced neoplasia (advanced polyps and colorectal cancer), satisfaction/trust with surveillance procedure
 - *Secondary:* major and minor harms, cancer worry, emotional benefits of surveillance, FIT performance characteristics, adherence and crossover, interval colorectal cancer

Cycle 3 2020 – PLACER Funding Slate

1 Recommended Addition to the Slate Approved by the Board in July



Project Title

Achieving Blood Pressure Goals After Stroke

Large pragmatic trial to prevent suicide attempts, deaths in moderate-to-high risk youth

PRECIDENTD (PREvention of Cardiovascular and Diabetic kidney disease in Type 2 Diabetes)

Specialty Compared to Oncology delivered Palliative Care for Patients with Acute Myeloid Leukemia (SCOPE-Leukemia)

THRIVE: Trajectories of Recovery after Intravenous Propofol vs inhaled Volatile anesthesia

Colonoscopy versus stool-based testing for older adults with a history of colon polyps

Note: All proposed projects, including requested budgets and project periods, are approved 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 additional project to the slate of awards from the Cycle 3 2020 PLACER 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

Voice Vote:

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

Limited Competition: Dissemination and Implementation PFA

Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Cycle 1 2021 Award Slate

Michael Herndon, DO

Chair, Engagement, Dissemination, and
Implementation Committee

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation Program



Project Title	
Implementation of an Online Weight Management Program in Clinical and Community Settings	
Total Funds Requested:	\$2.1M*

* All proposed projects, including requested budgets and project periods, are approved 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 award slate:
 - Cycle 1 2021 Limited Competition Dissemination and Implementation 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

Voice Vote:

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

Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research: PCORnet®, The National Patient-Centered Clinical Research Network - Phase 3

Cycle 1 2021

Barbara McNeil, MD, PhD
Chair, Selection Committee

Penny Mohr, MA
Acting Program Director
Research Infrastructure



Cycle 1 2021 – PCORnet®, The National Patient-Centered Clinical Research Network – Phase 3

PFA Overview



- **Objectives of this PFA:**
 - Optimize Clinical Research Network (CRN) capacity to serve as a national resource for conducting rapid, efficient, patient-centered CER that improves healthcare delivery and health outcomes
 - Optimize infrastructure to increase diversity of populations and care settings, efficiently implement research studies addressing PCORI's Strategic Research Priorities, strengthen patient and stakeholder engagement, and deliver high quality data
- **Limited competition PFA:** CRNs currently funded to participate in PCORnet
- **Posted Funds:** Up to \$60 million
- **Maximum project period:** 3 Years

- Hospitals
- Primary care practices
- Outpatient specialty care practices
- Emergency and urgent care centers
- Community clinics

*Normalized Area Deprivation Index (ADI) value. Quartile 1 represents the lowest level of "disadvantage" and Quartile 4 represents the highest level of "disadvantage"

Cycle 1 2021 – PCORnet®, The National Patient-Centered Clinical Research Network – Phase 3

Recommended Slate of 8 Projects



Project Title	
PEDSnet: Advancing Pediatric Patient-Centered Outcomes Research in PCORnet®	
The Stakeholders, Technology and Researchers (STAR) Clinical Research Network: Phase 3	
Greater Plains Collaborative Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research: PCORnet®, The National Patient-Centered Clinical Research Network – Phase 3	
OneFlorida+ Partner Engagement Network	
INSIGHT Clinical Research Network	
Accelerating Data Value Across a National Community Health Center Network (ADVANCE) Clinical Research Network (CRN)	
REACHnet 3.0: Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research	
PaTH to Health: PCORnet® Clinical Research Network	
Total Funds Requested	\$61M*

*All proposed projects, including requested budgets and project periods, are approved 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 1 2021 - PCORnet®, The National Patient-Centered Clinical Research Network – Phase 3 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

Voice Vote:

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

Proposed FY 2022 PCORI Budget

(October 1, 2021 – September 30, 2022)

Russell Howerton, MD

Chair, Finance and Administration Committee

Nakela L. Cook, MD, MPH

Executive Director

Projected FY 2021 Fund Balance

PROJECTED FUND BALANCE *	
Accrual Basis (\$ in millions)	
Actual Fund Balance at 9/30/2020	\$ 1,381
Revenue (FY 2021)	493
Expenses (FY 2021)	(369)
Projected Fund Balance at 9/30/2021	1,505
Projected Outstanding Award Obligations at 9/30/2021	(1,026)
Net Funds Available at 9/30/2021 **	\$ 479

* Includes PCOR Trust Fund and bank accounts.

** These funds are available for new award commitments and operating costs.

Projected FY 2022 Fund Balance



PROJECTED FUND BALANCE *	
Accrual Basis (\$ in millions)	
Projected Fund Balance at 9/30/2021	\$ 1,505
Revenue (FY 2022)	529
Expenses (FY 2022)	(404)
Projected Fund Balance at 9/30/2022	1,630
Projected Outstanding Award Obligations at 9/30/2022 **	(1,314)
Net Funds Available at 9/30/2022 ***	\$ 316

* Includes PCOR Trust Fund and bank accounts.

** Outstanding award obligations include assumptions about the planned commitment amounts in FY 2022 and are subject to change.

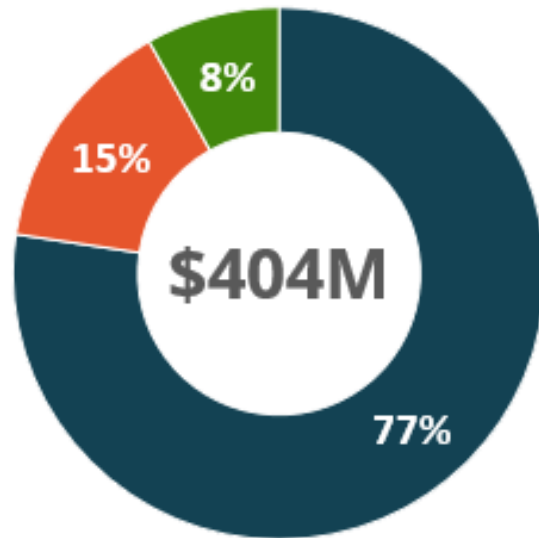
*** These funds are available for new award commitments and operating costs.

Proposed FY 2022 PCORI Budget

By Major Component



Proposed FY 2022 Budget



- 77%** Award Payments
- 15%** Programs & Program Operations
- 8%** Administrative Support

	FY 2022 Proposed Budget		FY 2021 Projection		FY 2021 Approved Budget				
	\$ in millions								
REVENUE	\$	528.6		\$	493.4	\$	524.8		
EXPENSES									
PROGRAM SERVICES									
Award Payments *		312.8	77%	297.3	81%	317.7	80%		
Programs & Program Operations		58.7	15%	45.1	12%	52.5	13%		
TOTAL PROGRAM SERVICES		371.5	92%	342.4	93%	370.2	93%		
ADMINISTRATIVE SUPPORT		32.8	8%	26.4	7%	29.1	7%		
TOTAL EXPENSES	\$	404.3	100%	\$	368.8	100%	\$	399.3	100%

* Award payments are estimated expenses and are based predominantly on fully executed contracts for award commitments approved in prior years. PCORI management uses historical billing data to predict award payment amounts by research and other awardees over the period of a project which spans over multiple years.

Board Vote

Call for a Motion to:

- **Approve** the proposed FY2022 budget

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

BREAK

We will return at 3:55 PM ET



Join the conversation on Twitter via
@PCORI

Congressional Panel: Health Policy Landscape

The Honorable Senator Bill Cassidy, MD (R-LA)

Closing Remarks

Wrap Up and Adjournment

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