

Board of Governors Meeting via Teleconference/Webinar

September 26, 2017

12:00 - 1:30 pm ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director



Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00-12:05	Consider for Approval: Consent Agenda
12:05–12:25	Consider for Approval: FY 2018 Budget
12:25-12:40	Consider for Approval: PCORnet Coordinating Center Task Order Set-aside Usage
12:40-12:55	Consider for Approval: American Heart Association-PCORI Collaboration
12:55-1:15	Consider for Approval: Process for Dissemination & Implementation Awards
1:15-1:30	Consider for Approval: Additional Application from the Cycle 3, 2016 PCS PFA
1:30	Wrap up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director



Motion for Consent Agenda

That the Board approve:

- Minutes from September 12, 2017 Board meeting
- Nomination of Kevin Weinfurt to serve as the ethicist member of the Advisory Panel on Clinical Trials (CTAP) through Fall 2020



Board Vote

Call for a Motion to:

- **Approve** each of the Motions on the Consent Agenda

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 FY2018 PCORI Budget (October 1, 2017 – September 30, 2018)

Larry Becker

Chair, Finance and Administration Committee

Regina Yan, MA

Chief Operating Officer



Agenda

- Key Definitions
- Funding Commitment Plan
 - PCORI Estimated Revenue and Expenditures
 - Funding Commitment Plan: Through FY2018
 - Cumulative Award Commitments vs. Award Payments
 - Total Revenue vs. Total Expenditures per Year
- Fund Balances
 - Projected FY2017 Fund Balance
 - Projected FY2018 Fund Balance
- FY2018 Budget Overview
 - Budget Development Process
 - Key Budget Themes
 - FY2018 Budget: By Major Component
 - FY2018 Proposed vs. FY2017 Projection
- Motion to Approve



Key Definitions

Award Commitments – the amount of funding PCORI intends to award or has awarded, most in the form of multi-year contracts for research, infrastructure, engagement, and dissemination awards

Award Payments – the amount PCORI pays to research, infrastructure, and engagement/dissemination awardees in response to invoices received for costs incurred under awarded contracts

- Note: Award commitments occur earlier than award payments. Award payments lag award commitments and the associated payments are spread over multiple years

Program Expenses – all program award payments, as well as all direct operating costs (including personnel associated with the Science, Infrastructure, Engagement, and Dissemination departments, as well as the Methodology Committee)

Program Support – all operating costs, including personnel, associated with the Evaluation & Analysis, Contract Management & Administration, and Communications departments

Administrative Support – all operating costs, including personnel, associated with the Board of Governors/Governance, Office of the Executive Director, General Counsel, and Office of the Chief Operating Officer, which also includes Information Technology, Finance, Procurement, Human Resources, and Administrative Services



PCORI Estimated Revenue and Expenditures

	In Millions	% of Total Expenditures
Revenue (thru FY2019)	\$ 3,245	
Program Expenses (thru FY2024)	\$ 2,955	91%
Award Payments (Research/Infrastructure/Engagement/Dissemination/AHRQ Workforce Training)	2,742	85%
Other Program Expenses	213	6%
Program Support (thru FY2024)	\$ 94	3%
General Admin (thru FY2024)	\$ 196	6%
Total Expenditures	\$ 3,245	100%

Other Program Expenses: Includes all direct operating costs (including personnel) associated with the Science, Research Infrastructure, Engagement, and Dissemination departments, as well as the Methodology Committee

Program Support: Includes all operating costs (including personnel) associated with the Evaluation & Analysis, Contract Management & Administration, and Communications departments

General Admin: Includes costs related to the Board, administrative staff, rent, IT system infrastructure, etc.



Funding Commitment Plan (through FY2018)

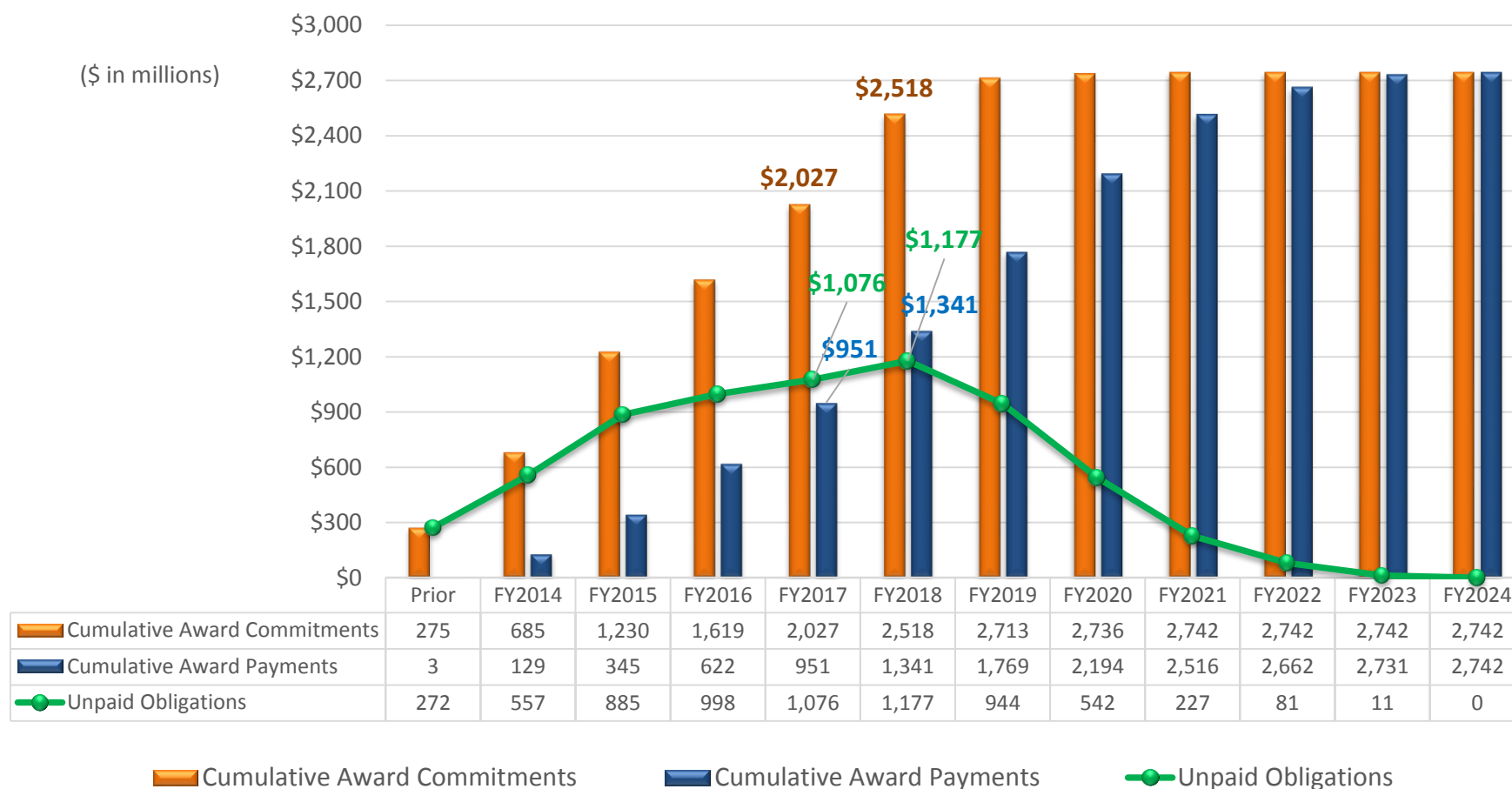
At the end of FY2018, PCORI plans to have committed approximately \$2.518 billion, or 92%, of its total award commitment funds of \$2.742 billion

COMMITMENTS (\$ in millions)	Prior	FY2017 Projection	FY2018 Proposed	Cumulative as of Sep 30, 2018
Research Awards (Science)	\$ 1,223	\$ 325	\$ 382	\$ 1,930
PCORnet Research Awards	58	7	29	94
PCORnet Infrastructure Awards	296	37	32	365
Engagement and Pipeline to Proposal Awards	42	27	21	89
Dissemination Program Activities	-	6	22	28
AHRQ Workforce Training Award	-	6	6	12
Total Commitments	\$ 1,619	\$ 408	\$ 491	\$ 2,518



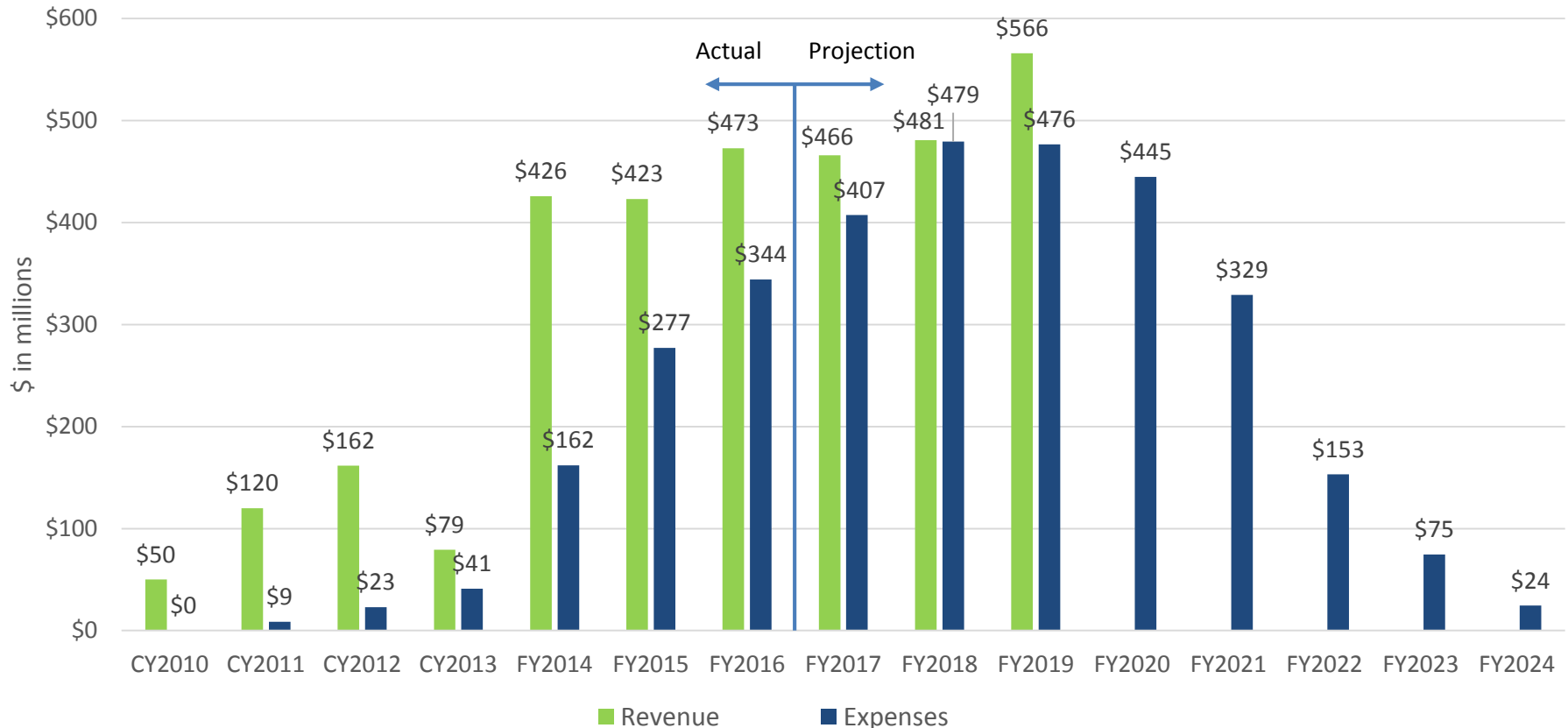
Cumulative Award Commitments vs. Award Payments

\$2.7 billion will be committed by 2021 (including Dissemination Awards and AHRQ Workforce Training). Award Payments are anticipated to continue through 2024



Total Revenue vs. Total Expenditures Per Year

PCORI has modeled its cash flow to ensure proper management and closing out of research obligations and operations expected to occur through 2024 based on revenue received through 2019



Note: In calendar year 2013, the Board of Governors voted to change the financial reporting period for PCORI to a fiscal year that begins on October 1 and ends on September 30 of each year. Total revenues and expenses for the nine-month fiscal year of January 1 through September 30, 2013 are presented for illustration purposes



Projected FY2017 Fund Balance

PROJECTED FUND BALANCE Accrual Basis (\$ in millions)	
Fund Balance at September 30, 2016	\$ 876
Revenue (FY2017)	466
Expenses (FY2017)	(407)
Projected Fund Balance at September 30, 2017	\$ 935



Projected FY2018 Fund Balance

PROJECTED FUND BALANCE Accrual Basis (\$ in millions)	
Fund Balance at September 30, 2017	\$ 935
Revenue (FY2018)	481
Expenses (FY2018)	(479)
Projected Fund Balance at September 30, 2018	\$ 937



Annual Budget Development Process

PCORI's budget is developed through a comprehensive process grounded in its strategic plan



FY2018 Budget Overview

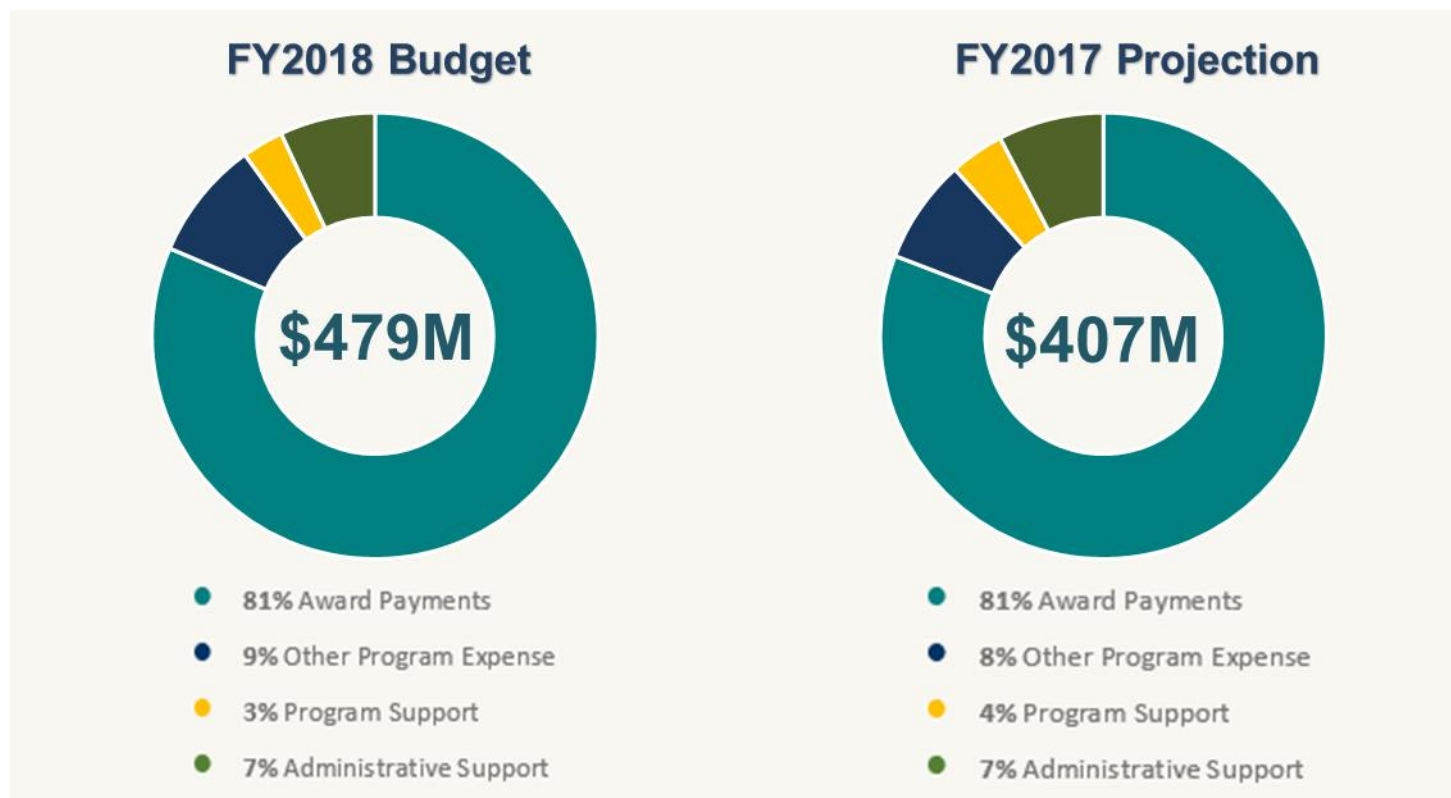
Key Budget Themes

- **Increase in Award Payments**
 - *\$1.9 billion awarded (as of September 12, 2017)*
- **Peer Review of PCORI-Funded Research**
 - *Expect an increase as more research projects reach their completion*
- **Dissemination and Implementation Program**
 - *Expect an increase in available research findings*



FY2018 Budget Overview: By Major Component

- **\$478.6 million** proposed FY2018 consolidated budget:
 - \$71.2 million (17%) over \$407.4 million FY2017 projected expenses



While the total budget and award payments continue to grow, the proportion of costs for all major budget categories remains about the same



FY2018 Budget Overview: By Major Component

	2018 Budget	
REVENUE	\$ 480,852,000	
EXPENSES		
PROGRAM EXPENSES		
(Award Payments & Program Expenses)		
Research	288,955,457	
Infrastructure (PCORnet, Workforce Training)	94,930,485	
Engagement	40,177,699	
Dissemination	7,485,070	
TOTAL PROGRAM EXPENSES	431,548,711	90%
PROGRAM SUPPORT		
Communications	6,862,894	
Contracts Management & Administration	3,865,876	
Evaluation & Analysis	3,516,431	
TOTAL PROGRAM SUPPORT	14,245,201	3%
ADMINISTRATIVE SUPPORT		
Board of Governors/Governance	795,903	
Management and General	32,037,619	
TOTAL ADMINISTRATIVE SUPPORT	32,833,522	7%
TOTAL EXPENSES	\$ 478,627,434	100%



FY2018 Budget vs. FY2017 Projection

PROPOSED FY2018 PCORI BUDGET

	2018 Budget		2017 Projection		FY'18 Budget vs. FY'17 Projection	
					\$ Var	% Var
REVENUE	\$ 480,852,000		\$ 465,738,811		\$ 15,113,189	3%
EXPENSES						
PROGRAM EXPENSES						
(Award Payments & Program Expenses)						
Research	288,955,457		249,962,430		38,993,026	16%
Infrastructure (PCORnet, Workforce Training)	94,930,485		79,078,156		15,852,329	20%
Engagement	40,177,699		27,267,807		12,909,891	47%
Dissemination	7,485,070		3,874,522		3,610,549	93%
TOTAL PROGRAM EXPENSES	431,548,711	90%	360,182,916	89%	71,365,795	20%
PROGRAM SUPPORT						
Communications	6,862,894		5,897,883		965,011	16%
Contracts Management & Administration	3,865,876		6,235,476		(2,369,600)	(38%)
Evaluation & Analysis	3,516,431		3,856,640		(340,208)	(9%)
TOTAL PROGRAM SUPPORT	14,245,201	3%	15,989,998	4%	(1,744,797)	(11%)
ADMINISTRATIVE SUPPORT						
Board of Governors/Governance	795,903		795,903		-	0%
Management and General	32,037,619		30,407,249		1,630,370	5%
TOTAL ADMINISTRATIVE SUPPORT	32,833,522	7%	31,203,152	7%	1,630,370	5%
TOTAL EXPENSES	\$ 478,627,434	100%	\$ 407,376,066	100%	\$ 71,251,368	17%



Board Vote

Call for a Motion to:

- **Approve** the Proposed FY2018 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**

Roll Call Vote:

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



Coordinating Center (CC) Phase II Set Aside Funding

Joe Selby, MD, MPH
Executive Director



PCORnet Phase II Coordinating Center Funding

- Phase II Funding Approvals:
 - 1/15/16 RTC endorsed funding for Genetic Alliance (GA) Phase II Funding
 - 2/18/16 RTC endorsed funding for Duke Phase II and “set-aside funding” which was intended to be used for either the Duke Clinical Research Institute (Duke) or GA portions of the Coordinating center
 - 2/23/16 PCORI Board of Governors approved funding for overall Phase II Coordinating Center (GA, Duke, and set-aside funding)

Breakdown of Funding Endorsed by the RTC and Approved by the Board	
GA Phase II Funding	\$2,591,040
Duke Phase II Funding	\$24,541,034
Set Aside Funding	<u>\$ 4,500,000</u>
Total Duke Phase II Funding	\$29,041,034
Total Funding	\$31,632,074



Rationale for “Set-Aside” Funding

- With the beginning of Phase II, PCORI staff introduced the concept of the “task order set aside” system and included it in Duke and Genetic Alliance Coordinating Center contracts to allow for activity-by-activity negotiation
 - Set aside funds were intended by PCORI staff for use by either Duke and Genetic Alliance
 - The task order set aside system has given PCORI the flexibility to expand the scope of the Coordinating Center work sequentially during Phase II as the evolving needs and next steps for PCORnet became clear
 - The needs are identified through our program management and oversight of the Coordinating Center and PCORnet networks



Slight Adjustment in “Set Aside” Funds Approval

- **RTC formal endorsement language (2/18/16):** “Endorse \$29,041,034 in total costs for Duke for PCORnet Coordination in Phase II from April 1 2016- November 30, 2018” – inadvertently lumped the Duke funding with the set-aside funds
- **Board formal approval language (2/23/16):** “Approve \$29 million in total costs for Phase II PCORnet Coordinating Center Activities for Duke Clinical Research Institute” – same issue
- The set-aside funds were formally approved as part of Duke’s funding, rather than as funding that could be used flexibly for new Coordinating Center activities by either Duke or Genetic Alliance



Coordinating Center Phase 2 Task Orders

Organization	Funding Source		Total Task Orders
	Phase II Contract	Set Aside Funds	
Duke	11	1 (modification)	11
Genetic Alliance	3	2 (modifications) 5 (new task orders)	8



Breakdown of Coordinating Center Funding

Organization	Board Approval Amount	Committed as of July 25, 2017
Duke University	\$24,541,034	\$24,732,057
Genetic Alliance	\$2,591,040	\$4,188,609*

* Includes Phase I carry over funds

Breakdown of Set Aside Funding as of July 25, 2017

Set Aside Funding	Amount Committed to GA	Amount Committed to Duke	Remaining
\$4,500,000	\$1,338,169	\$191,023	\$2,970,808



Lessons Learned & Future Set Aside Funding

- The concept of set-aside funding has worked very well, providing flexibility to PCORI staff to meet PCORnet's fluid needs relatively quickly as the needs are identified and appropriate activities identified
- The original approval language and our proposed correction have been presented to both the RTC and the FAC and each committee endorses the usage of Coordinating Center set aside funding for either Duke or Genetic Alliance Coordinating Center activities
 - RTC endorsed on August 18, 2017
 - FAC endorsed on August 22, 2017
- Current plans for the remaining \$2.97M include:
 - Query Fulfillment Decentralization
 - Modification to Commons Task Order



Board Vote

Call for a Motion to:

- **Approve** the use of PCORnet Coordinating Center set aside funding for either Duke or Genetic Alliance

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



AHA-PCORI Collaboration: Shared Decision Making and Patient Care for those with Atrial Fibrillation at Risk for Stroke

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Evelyn P. Whitlock, MD, MPH

Chief Science Officer



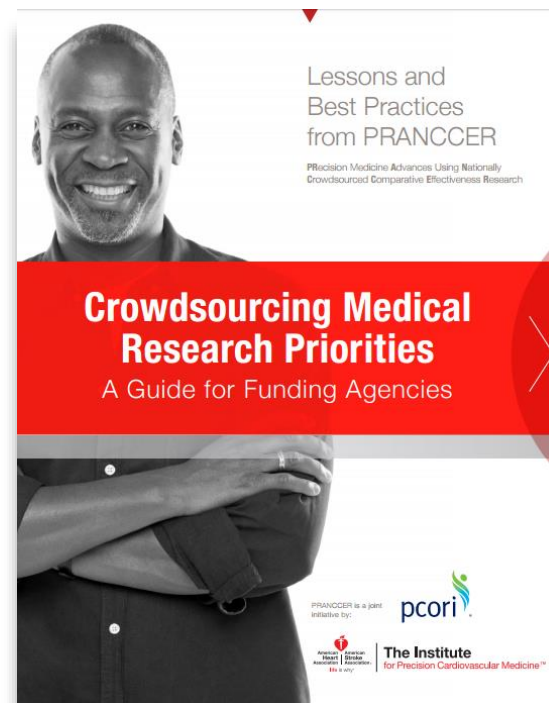
Origin of the AHA-PCORI Collaboration

- Precision Medicine Advances using Nationally Crowdsourced CER (PRANCCER) originated with the PCORI Research Transformation Committee in the fall of 2015
- The goal was to conduct crowdsourcing challenges to identify critical, patient-centered, comparative effectiveness research cardiovascular disease questions that would further precision medicine approaches for cardiovascular disease treatment and prevention



PRANCCER Results

1. Completed a challenge for patients and a subsequent challenge for researchers, and top questions were identified
2. Created a “blueprint” with lessons learned and recommendations for using the crowdsourcing mechanism to identify CER questions in the future



Proposed Research Collaboration

- Top research topics from PRANCCER included treatment options to prevent stroke in patients with atrial fibrillation
- In November 2016, AHA announced that it would commit \$2.5M to fund research emanating from PRANCCER
- PCORI provided AHA with a letter of intent to match the funds with \$2.5M, pending identification of an appropriate research project



Rationale for Proposed Project

- A PCORI-commissioned ECRI Institute topic brief documented underuse of anticoagulants in patients with atrial fibrillation (A-Fib) and found that lack of both clinician adherence to guidelines and patient adherence to medication contributed to underuse
- A recent systematic review* about research on decision aids (DA) for treatment options found only one published study that included newer oral anticoagulants and that no DAs were currently available for clinical use
- AHA proposed taking advantage of a planned program for a Strategically-Focused Research Network (SFRN) on A-Fib for a project; a funding announcement was planned for September



*O'Neill, et al. Am Heart J 2017;191:1-11.

Current Proposal: DECIDE

- **Project Title:** Decision-making and Choices to Inform Dialogue and Empower A-Fib Patients (DECIDE)
- **Goal:** Fund a center within the AHA SFRN to develop or adapt and test a decision aid to enable patients and clinicians to choose oral anticoagulant (OAC) options to prevent stroke in the setting of A-Fib and to enable shared decision making around OAC options
- The DECIDE center would collaborate with other centers in the SFRN to test the tool in appropriate patients and compare it with existing decision strategies
- AHA and PCORI will each contribute \$2.5M for one 4-year project. AHA will manage the award assuring PCORI requirements for stakeholder engagement, Merit Review, Peer Review of research findings, and public availability of results



DECIDE Requirements and Expectations

- Develop or adapt a decision aid (DA), including validation testing and insuring adherence to International Patient Decision Aid Standards (IPDAS)
- Ensure that the DA advises on risks of stroke and bleeding for various clinical situations and treatment options and utilizes current guideline-based clinical recommendations
- Include both patient-facing and clinician-facing materials
- Encourage innovative approaches in the DA design and administration
- Test in a broadly representative population, including a range of stroke and bleeding risk, age, and co-morbidity, and assure applicability to patients with a range of health literacy and numeracy



DECIDE Requirements and Expectations

- Compare the DA with other existing tools or education strategies
- Test for outcomes of knowledge, decision conflict, satisfaction with decision, care concordant with patient preferences, shared decision-making, prescription of an OAC, adherence to an OAC, and clinical outcomes, at least as a secondary outcome
- Adherence to PCORI requirements for Merit Review, Methodology Standards, and Peer Review, including public reporting
- Time frame:
 - Posting of the RFA by September 30, 2017
 - Award made by June 30, 2018



Proposed Funding Structure

PCORI Contribution to Initiative	\$2,500,000
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PCORI Contribution to AHA Administrative Costs	\$250,000
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Total PCORI Contribution to Initiative	\$2,750,000
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AHA/ASA Contribution to Initiative	\$2,500,000
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Total AHA/ASA Contribution to Initiative	\$2,500,000
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Board Vote

Call for a Motion to:

- **Approve** PCORI funding up to \$2.75M to support the AHA-PCORI Collaboration: DECIDE, a 4-year project, subject to terms of agreement between PCORI and AHA

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



Process for Approval of Large Dissemination & Implementation Awards

Debra Barksdale, PhD, RN

Chair, Engagement, Dissemination & Implementation Committee

Jean R. Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer



Purpose

To implement a process consistent with PCORI policy for approval of large (>\$500k) Dissemination & Implementation awards

- Consistent with PCORI policies on Conflict of Interest
- Extending processes currently in place for D&I awards of \$500k or less



Current D&I Funding Opportunities

This approval process will apply to all D&I awards over \$500k across D&I funding mechanisms. Currently these are:

- 1. Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results (“Limited Competition”)**
 - Offered 3 cycles per year since Cycle 1 2016
 - Standard award is \$350k total direct costs, 2 year maximum
 - “Greater than request” available
- 2. Implementation of Effective Shared Decision Making Approaches in Practice Settings**
 - First cycle now open (Off-cycle 2 2017), additional cycle in 2018
 - \$1.5M total direct costs, 3 year maximum



Background

- **To date, the D&I Program has not recommended projects over \$500k for funding**
 - Implementation of Shared Decision Making PFA has just opened
 - Only standard D&I Limited Competition awards have been recommended for approval (\$350k per project direct costs; ≈\$490k total award)
 - Consistent with PCORI policy, the Chief Engagement and Dissemination Officer (CEDO) has approved awards that are \$500k or less*

**Delegation of Authority and Expenditure Approval Policy, Board Approved 9.27.16*



Need for Approval Process for Larger Awards

- D&I Limited Competition PFA does allow applicants to request project funds in excess of the standard award (“**Greater Than Request**”)
 - Greater Than Requests are encouraged for high-impact results and for collaborative projects that include multiple PCORI findings
 - At the Letter of Intent (LOI) stage, the D&I Program approved 4 applicants to submit Greater Than Requests for Cycle 1 2017*
 - These applicants submitted proposals ranging from \$700k - \$1.2M
- First applications to the Shared Decision Making Implementation PFA (up to \$2.3M total awards) will go to Merit Review in January 2018

**D&I Limited Competition applicants must justify their intention to submit a Greater Than application at the LOI stage. D&I Program staff review LOIs and present recommended projects to the CEDO for input before issuing LOI decisions to applicants*



Proposed Approval Process for Large Awards

- The D&I Program will present the slate of projects over \$500k being recommended for funding to the Engagement, Dissemination and Implementation Committee (EDIC) for consideration and approval to move forward for presentation to the Board of Governors
 - The D&I Program will develop a process and corresponding SOP for presenting recommended projects to the EDIC based on existing PCORI precedents and policies
- The slate of projects that the EDIC approves to move forward will be presented to the PCORI Board of Governors for approval
- The Approval Process for awards of \$500k or less will not be affected
- On August 1, 2017, EDIC recommended that the Board approve the Program Plan and Approval Process for Large Dissemination & Implementation Awards



Board Vote

Call for a Motion to:

- **Approve** the Approval Process for Large Dissemination & Implementation Awards

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



Additional Proposed Study

Cycle 3 2016 Pragmatic Clinical Studies

Award Slate

Christine Goertz, DC, PhD
Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH
Chief Science Officer



Pragmatic Clinical Studies

Cycle 3 2016 Funding Slate – 1 Additional Project

Project
PRO-ACTIVE: Comparing the Effectiveness of Prophylactic Swallow Intervention for Patients Receiving Radiotherapy for Head and Neck Cancer
PREPARE: Pragmatic Randomized Trial Evaluating Pre-Operative Antiseptic Skin Solutions in Fractured Extremities
Comparative Effectiveness of School-Based Caries Prevention Programs for Children in Underserved, Low Income, Hispanic Communities
A Pragmatic Trial of Home versus Office-Based Narrow Band Ultraviolet B Phototherapy for the Treatment of Psoriasis



Pragmatic Clinical Studies – Cycle 3 2016

Slate Overview

Approved
3
Projects

Proposed
3 + 1 = 4
Projects

Previously Approved Award	Proposed Total Award*
\$32.8M	\$41.4M

* 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



Additional Project: A Pragmatic Trial of Home versus Office Based Narrow Band Ultraviolet B Phototherapy for the Treatment of Psoriasis

- **Research Question:** Is home-based phototherapy non-inferior to office-based phototherapy for treatment of patients with moderate to severe psoriasis in terms of clinical and patient-reported outcomes?
- **Population:** Adults with moderate to severe psoriasis
- **Intervention/Comparator(s):**
 - Home-based narrow band ultraviolet B (UVB) treatment
 - Office-based narrow band UVB treatment

Outcomes of Interest:

- *Primary:*
 - Physician Global Assessment of skin (physician-reported)
 - Dermatology Life Quality Index (patient-reported)
- *Secondary:* Frequency and dosing of treatment, treatment compliance, treatment-emergent adverse events
- **Study Design:** Randomized Controlled Trial
 - Sample Size: 1050 at 40 sites
- **Length of Follow-up:** 24 weeks
- **Duration of Active Intervention:** 12 weeks
- **Total Project Cost:** \$8.6M



Additional Project: A Pragmatic Trial of Home versus Office Based Narrow Band Ultraviolet B Phototherapy for the Treatment of Psoriasis

- **Potential Impact:** Should the study demonstrate that home-based therapy is non-inferior to office-based therapy, this could reduce patient burden (time, transportation) and expand access to an effective treatment option for patients with psoriasis
- **Patient-Centeredness:** The study team worked with patients and with a nonprofit organization that serves people with psoriasis and psoriatic arthritis to develop the project and select study outcomes
- **Engagement:** Dermatologists, patients, psoriasis experts, advocacy organizations, patient research partners, and payer community partners were involved in the design, selection of outcomes, and creation of the research question



Board Vote

Call for a Motion to:

- **Approve** funding for the recommended additional award from the Cycle 3 2016 Pragmatic Clinical Studies 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



Wrap Up and Adjournment

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

