

Board of Governors Meeting

via Teleconference/Webinar

July 26, 2022
1:00 PM – 2:55 PM

Welcome and Call to Order

Sharon Levine, MD

Vice Chairperson, Board of Governors

Agenda

Time	Agenda Item
1:00pm	Welcome, Call to Order, and Consider for Approval: June 14, 2022 Meeting Minutes
1:10-1:35	Consider for Approval: Advisory Panel Members, Chairs and Co-Chairs
1:35-2:20	Consider for Approval: Set of Candidate Topic Themes for Focused Funding
2:20-2:35	Update on Research Awards and Dissemination and Implementation Awards
2:35-2:50	FY 2022 Mid-Year Financial Results
2:50-2:55	Closing Remarks
2:55pm	Wrap-up and Adjourn

Board Vote

Call for a Motion to:

- **Approve** Minutes of the June 14, 2022, Board of Governors 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

Approval of Advisory Panel Members, Chairs and Co-Chairs

Michael Herndon, DO
Chair, Engagement, Dissemination,
and Implementation Committee

Alicia Fernandez, MD
Chair, Science Oversight Committee

Steven Goodman, MD, MHS, PhD
Chair, Methodology Committee

Kristin L. Carman, PhD, MA
Director, Public & Patient Engagement

Steven Clauser, PhD, MPA
Program Director, Healthcare Delivery
and Disparities Research

Kim Bailey, MSc
Associate Director, Clinical
Effectiveness and Decision Science

Anne Trontell, MD, MPH
Associate Director, Clinical
Effectiveness and Decision Science

Advisory Panel Selection Process

**Application
opened:
September
2021**

**Stakeholder
outreach:
September
2021 – March
2022**

**Application
deadline:
March 2022**

**Review and
endorsement of
slates by their
relevant
committees:
July 2022**

**Consideration
of slates by
Board of
Governors:
July 26, 2022**

Proposed Panelists for the Advisory Panel on Patient Engagement

Kristin L. Carman, PhD, MA
Director, Public and Patient Engagement

Advisory Panel on Patient Engagement (PEAP)

Proposed Panelists



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Agatha Onyinyechukwu Adigwe	Patients, Caregivers, and Patient Advocates	MA	3 years
Ramona Burress	Industry	IL	3 years
Gwen Cooper	Patients, Caregivers, and Patient Advocates	IN	3 years
Heidi Dohse	Patients, Caregivers, and Patient Advocates	ID	3 years
David Hwang	Clinicians	NC	3 years
Isabelle Lousada	Patients, Caregivers, and Patient Advocates	MA	3 years
Aracely Rosales	Patients, Caregivers, and Patient Advocates	FL	3 years

Advisory Panel on Patient Engagement (PEAP)

Proposed Chair and Co-Chair



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Proposed Chair			
Karen Fortuna	Researchers	NH	1 year
Proposed Co-Chair			
Jen Brown	Patients, Caregivers, and Patient Advocates	IL	1 year

Proposed Panelists for the Advisory Panels on Healthcare Delivery & Disparities Research and Rare Disease

Steven Clauser, PhD, MPA

Program Director, Healthcare
Delivery and Disparities Research

Advisory Panel on Healthcare Delivery & Disparities Research (HDDR AP)



Proposed Panelists

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Billy Collins	Clinicians	MD	3 years
Mark Friedberg	Payers	MA	3 years
Venus Gines	Patients, Caregivers, and Patient Advocates	TX	3 years
Heather Himelhoch	Hospitals/Health Systems	IL	3 years
Dipti Itchhaporia	Clinicians	CA	3 years
Feylyn Lewis	Researchers	TN	3 years

Advisory Panel on Healthcare Delivery & Disparities Research (HDDR AP)

Proposed Panelists



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Aasim Ilyas Padela	Researchers	WI	3 years
Katherine Sanchez	Hospitals/Health Systems	TX	3 years
Betty Scull	Patients, Caregivers, and Patient Advocates	AR	3 years
Jeffrey Tom	Payers	HI	3 years
Rosemary Veniegas	Hospitals/Health Systems	CA	3 years
Aileen Wong	Clinicians	AZ	3 years

Advisory Panel on Healthcare Delivery & Disparities Research (HDDR AP)

Proposed Chair and Co-Chair



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Proposed Chair			
Varleisha Gibbs	Researchers	MD	1 year
Proposed Co-Chair			
Brandi Ring	Clinicians	IL	1 year

Advisory Panel on Rare Disease (RDAP)

Proposed Panelists



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Danielle Dong	Industry	MA	3 years
Aliza Fink	Patients, Caregivers, and Patient Advocates	MD	3 years
Meghan Halley	Researchers	CA	3 years
Christy Moore	Payers	CA	3 years
Richard Parad	Researchers	MA	3 years

Advisory Panel on Rare Disease (RDAP)

Proposed Co-Chair



Name	Stakeholder Group	State	Term Length (or until replacement is appointed)
Heather Adams	Researchers	NY	2 years

Proposed Panelists for the Advisory Panel on Clinical Effectiveness and Decision Science

Kim Bailey, MSc

Associate Director, Clinical Effectiveness and
Decision Science

Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
Michael Fischer	Researchers	MA	3 years
Tom James	Payers	KY	3 years
Barry Liden	Researchers	MD	3 years
Yaara Zisman-Ilani	Researchers	PA	3 years

Advisory Panel on Clinical Effectiveness and Decision Science (CEDS AP)

Proposed Chair and Co-Chair



Name	Stakeholder Group	State	Term length (or until replacements are appointed)
Proposed Chair			
Julie Eller	Patients, Caregivers, and Patient Advocates	MA	1 year
Proposed Co-Chair			
Michael Hoerger	Clinicians	LA	2 years

Proposed Panelists for the Advisory Panel on Clinical Trials

Anne Trontell, MD, MPH

Associate Director, Clinical Effectiveness and
Decision Science

Advisory Panel on Clinical Trials (CTAP)

Proposed Panelists



Name	Stakeholder Group	State	Term Length (or until replacements are appointed)
M. Khair ElZarrad	Policymakers	MD	3 years
Alexander Fiks	Researchers	PA	3 years
Kelley Kidwell	Researchers	MI	3 years
Greg Merritt	Patients, Caregivers, and Patient Advocates	MI	3 years

Board Vote

Call for a Motion to:

- **Approve** the proposed slates of members, positions and terms for the following Advisory Panels: PEAP, HDDR AP, RDAP, CEDS AP, and CTAP

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

Set of Candidate Topic Themes: Planning for the Next Several Cycles of Focused Funding

Nakela L. Cook, MD, MPH

Executive Director

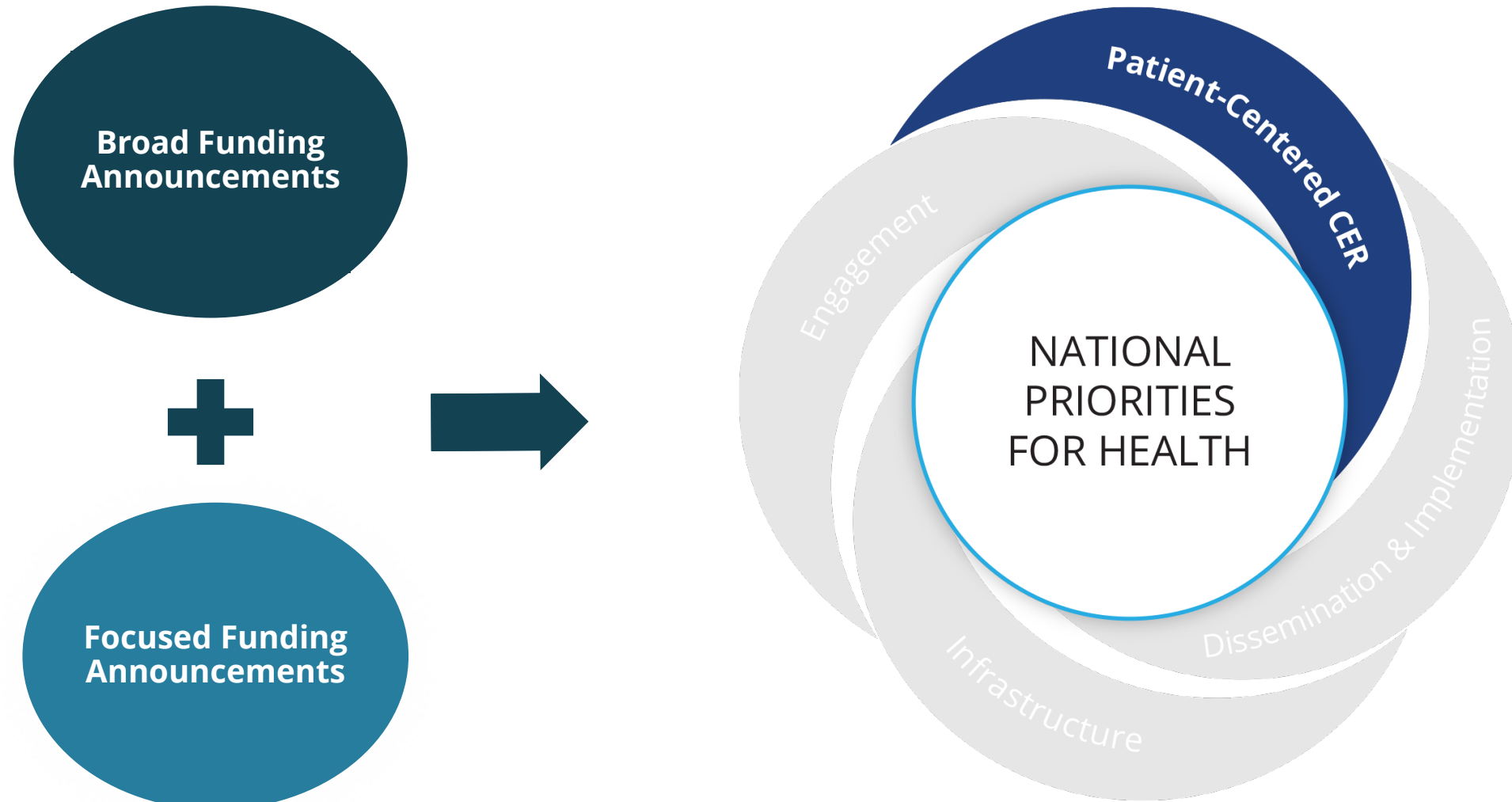
Harv I. Feldman, MD, MSCE

Deputy Executive Director for Patient-Centered
Research Programs

A Holistic Approach to Addressing Our National Priorities for Health



A Balanced Approach to Funding Patient-Centered Comparative Clinical Effectiveness Research



Focused Funding

2021

Expedited and enhanced approach while strategic planning was underway

To date: Resulted in **6 Special Areas of Emphasis, 12 Targeted PFAs, 4 approved topics in development**

2022

Transitional steps with strategic plan in place while refining process for setting Research Project Agenda

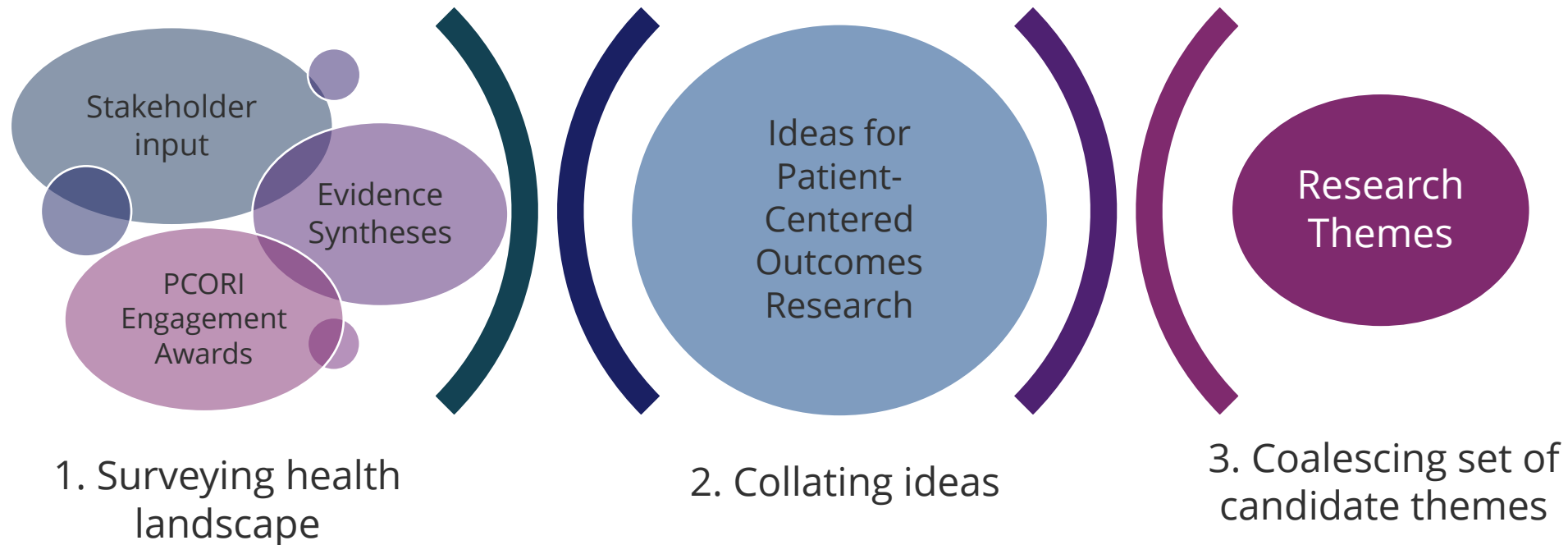
In July 2022, seeking Board approval for next **set of topic themes for next several cycles**

2023

Launch of our refined Research Project Agenda setting process for ongoing identification of topics for focused funding to complement our continuing broad PFAs open to all topics

Refining the **Research Project Agenda setting process**

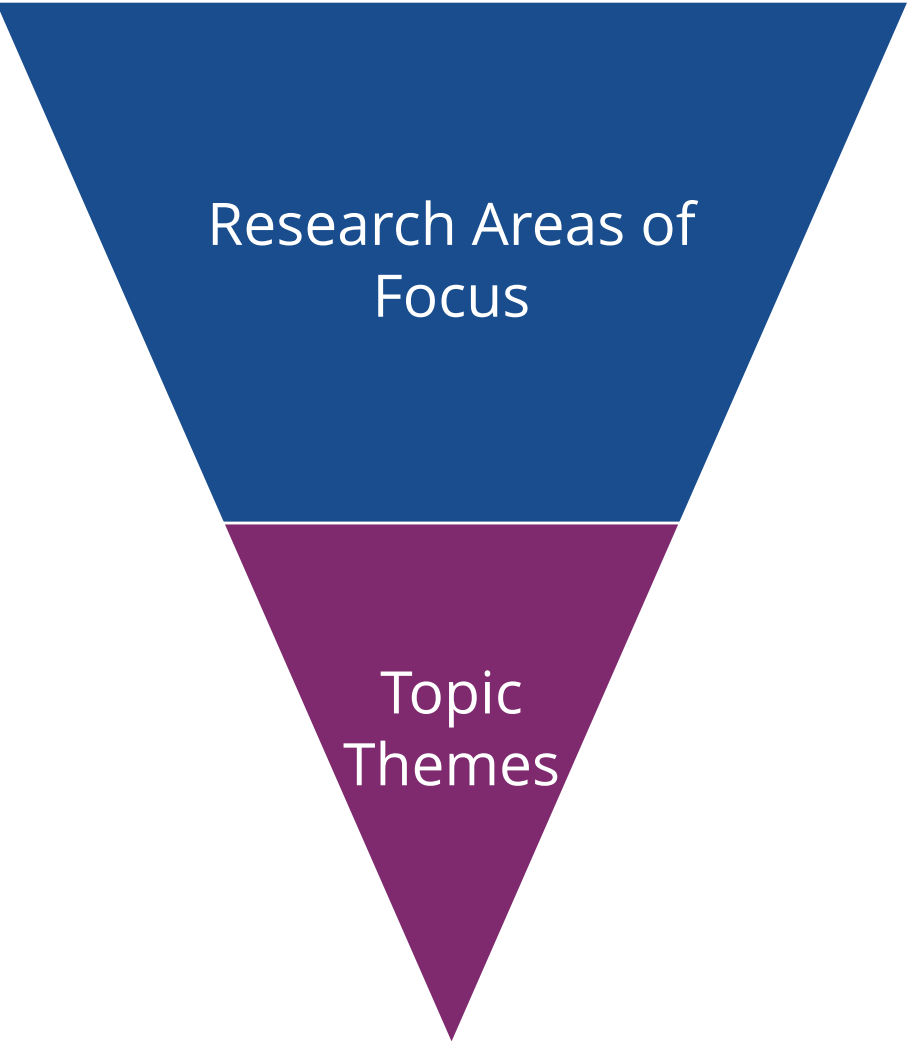
Advancing Thematic Areas as We Refine Our Process for Setting the Research Project Agenda



- Driven by our National Priorities for Health and advance the Research Agenda
- Represent high burden conditions or issues
- Resonate with multiple stakeholders
- Are areas where PCORI funding would make an impact

Coalescing Around Themes:

Moving from Inputs to Thematic Areas



Research Areas of
Focus

Research areas of focus

- Specific areas of focus within the topic theme with breadth to support a multipronged approach to address evidence gaps and improve care and outcomes

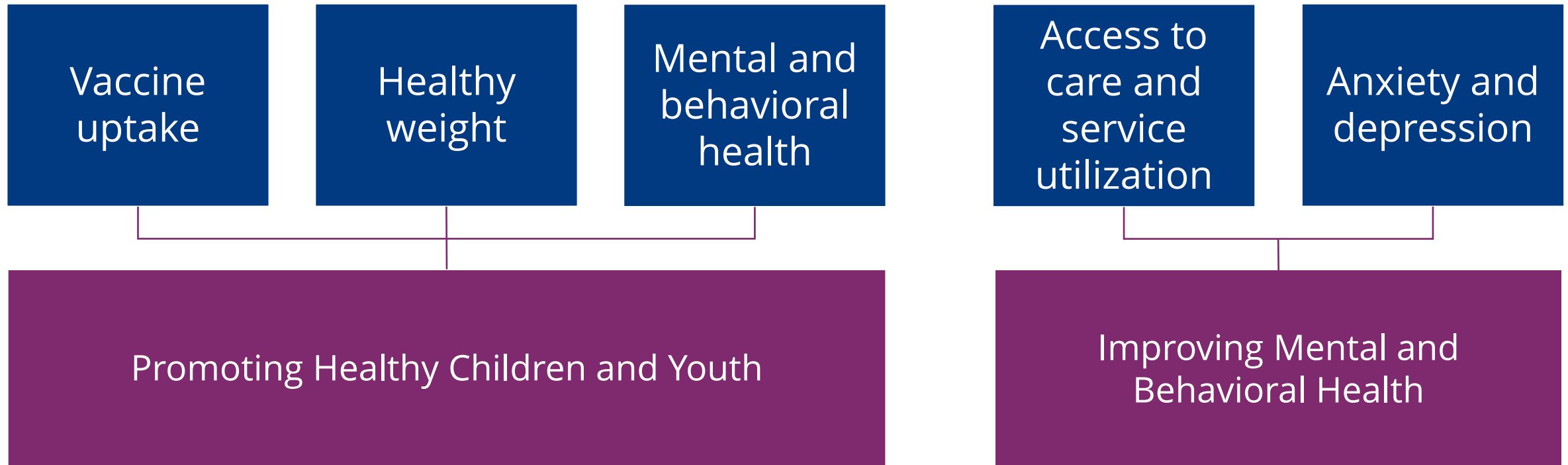
Topic
Themes

Topic themes

- Thematic areas (e.g., population, health conditions) for near-term focus that allow for flexibility and continued responsiveness to stakeholder input

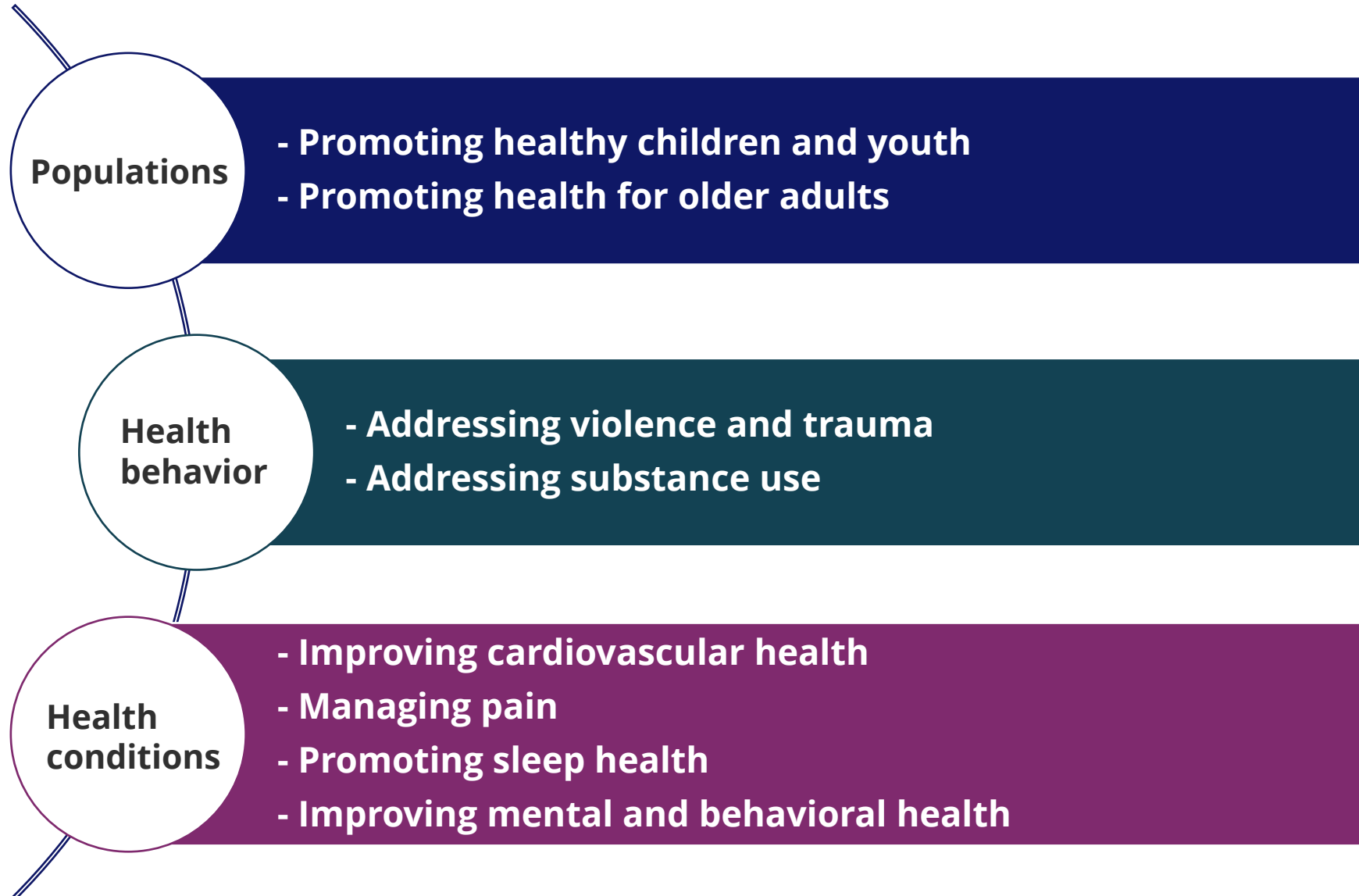
Examples of Two Candidate Topic Themes

Example research areas of focus



Topic Theme

Recommended Set of Candidate Topic Themes for Further Development

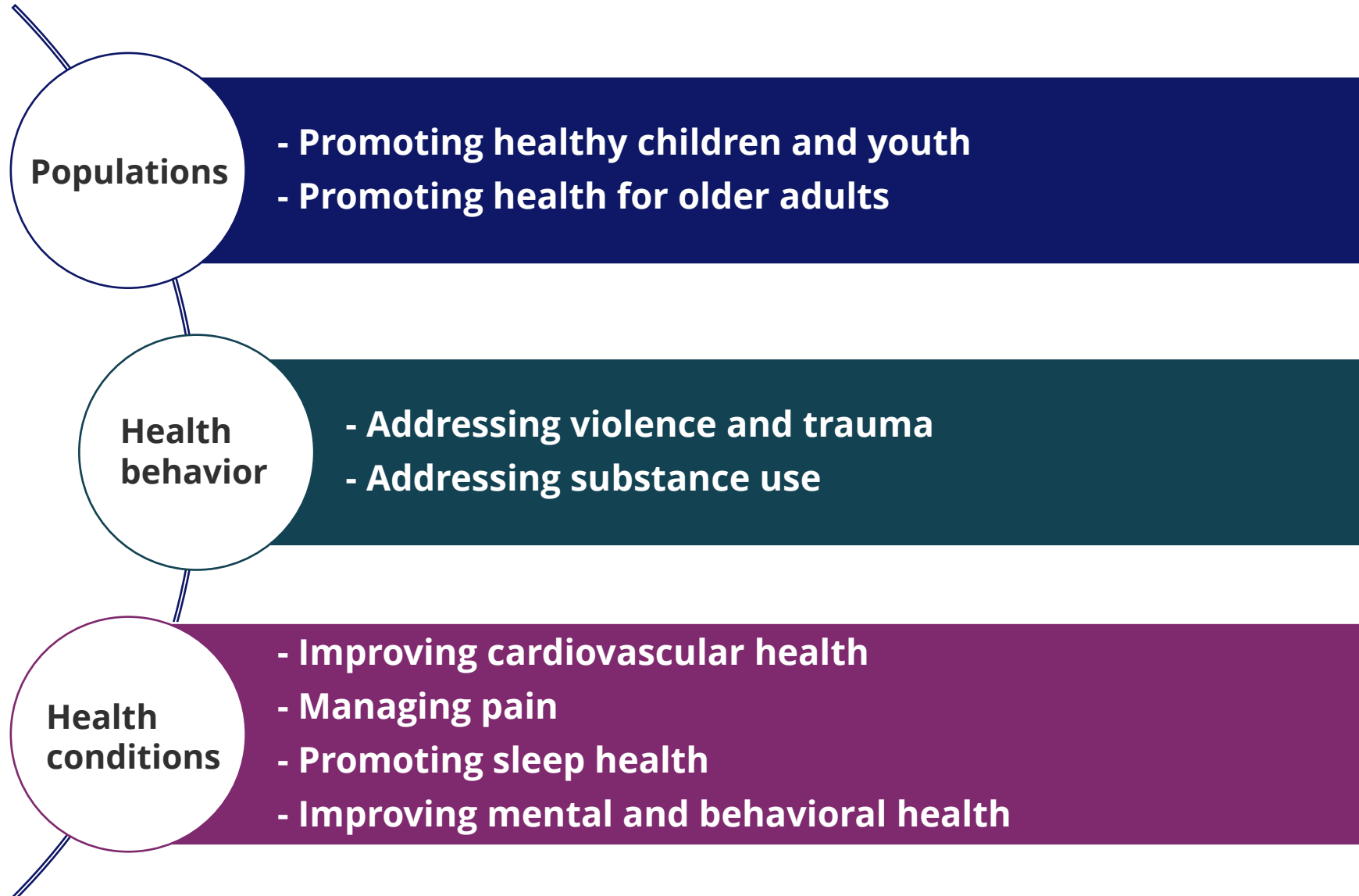


Work continues on the topics of improving outcomes for people with intellectual and/or developmental disabilities, preventing maternal morbidity and mortality, rare disease, and COVID-19

Discussion

- What makes these proposed Themes important for advancing PCORI's National Priorities for Health?
- How do you think that PCORI can most effectively approach these Themes?
- What additional considerations do you have for developing these Themes?

Recommended Set of Candidate Topic Themes for Further Development



Board Vote

Call for a Motion to:

- **Approve** the Recommended Set of Candidate Topic Themes for Further Development

Call for the Motion to be Seconded:

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

Voice Vote:

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

Update on Research Awards and Dissemination and Implementation (D&I) Awards

Nakela L. Cook, MD, MPH
Executive Director



Summary of Awards

PFA	Total Funding per PFA
Broad	\$64M
PCOR Methods	\$4M
Phased Large Awards for Comparative Effectiveness Research (PLACER)	\$139M
Targeted PFA: Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum	\$25M
Targeted PFA: Comparative Effectiveness of Novel Pharmacological and Evidence-Based Nonpharmacologic Treatments for Migraine Prevention	\$12M
Targeted PFA: Comparative Effectiveness of Multimodal Interventions to Prevent Osteoporotic Fractures	\$13M
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	\$4M
Total for all PFAs	\$261M*

* All project budgets proposed by awardees are subject to programmatic and budget approval by PCORI staff and the negotiation of a formal award contract.

Research Awards – Broad PFA

Project Title	Institution
Carolina Consortium to Improve BP Control in Vulnerable Populations	East Carolina University
Comparative Effectiveness of In-person and Telehealth Cardiac Rehabilitation	University of California San Francisco
Comparing Two Models of Well-Child Care for Black Families	Seattle Children's Research Institute
Comparing Three Approaches to Communication with Hospitalized Children with Limited English Proficiency	Boston Children's Hospital/ Harvard Medical School
COOL PRIME: Cooling Mild HIE Parental Selection of Outcomes	University of Texas Southwestern Medical Center
Future Planning and Well-Being for Individuals with Intellectual Disabilities and Family Caregivers	Feinstein Institute for Medical Research
LIVE-SMART: Liver Cirrhosis Interventions for Fall Preventions: A Sequential, Multiple Assignment Randomized Trial	University of Michigan
Preventing Suicidal Behavior with Diverse High-Risk Youth in Acute Care Settings	Johns Hopkins Bloomberg School of Public Health
Stent Omission after Ureteroscopy and Lithotripsy in Michigan Urological Surgery Improvement Collaborative (SOUL MUSIC)	University of Michigan
Text-Messaging Telehealth and Contingency Management for Opioid Use Disorder Treatment	University of Pennsylvania
Using Technology to Improve Maternal Mental Health & Substance Use Disorder Screening and Treatment	Medical University of South Carolina

Research Awards – PLACER and Methods PFAs

Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA	Institution
Cardiac Resynchronization Therapy using His/Left Bundle Pacing vs Left Ventricular Epicardial Pacing in Patients with Heart Failure (HF) with LVEF≤50% and a wide QRS complex (>130 ms) or with/anticipated >40% pacing (Left versus left randomized clinical trial)	Baylor College of Medicine
Individualizing Treatment for Asthma in Primary Care	DARTNet Institute
Nasal Steroids, Irrigation, Oral Antibiotics and Subgroup Targeting for Effective Management of Sinusitis	Georgetown University Medical Center
Rapid Reversal of Acute Suicidal Depression Across the Lifespan: A Pragmatic Comparative Effectiveness Trial of Electroconvulsive Therapy (ECT) vs. Intravenous Ketamine Treatment	Georgetown University Medical Center
Sequential Multiple Assignment Randomized Trial for Bipolar Depression: SMART-BD	Massachusetts General Hospital
Improving Methods for Conducting PCOR PFA	Institution
Improving PCOR/CER Study Methodologies in Studies with Different Respondent Types Using IRT	Brown University
Pragmatic Comparative Effectiveness Using Sequential Multiple Assignment Randomized Trials	University of Pittsburgh
Sensitivity Analysis Methods for Pragmatic Trials with Irregular and Informative Assessment Times	University of Utah
Statistical Methods for Optimizing Dynamic Patient-level Treatment and Monitoring Strategies	Memorial Sloan Kettering Cancer Center

Research Awards and D&I Awards

Targeted Research PFAs	Institution
<i>Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum</i>	
A Trial Comparing the Effectiveness and Tolerability of Medications in Older Adults with Stable Angina and Multiple Chronic Conditions: LIVE BETTER	Yale School of Medicine
Comparing Healthcare Visit Recording and Open Notes to Improve the Chronic Illness Care Experience for Older Adults (the CHRONICLE Trial)	Trustees of Dartmouth College
Perioperative Physical Activity in Older Adults Undergoing Lung Cancer Surgery	City of Hope
Comparative Effectiveness of Brief Strength and Balance Exercises and Standard Home-based Group Exercise for Primary Care Patients with Mobility Disability	Pennsylvania State University Hershey Medical Center
<i>Comparative Effectiveness of Novel Pharmacological and Evidence-Based Nonpharmacologic Treatments for Migraine Prevention</i>	
CBT via Telehealth + Amitriptyline Compared to CBT via Telehealth: Pediatric Migraine Prevention	Cincinnati Children's Hospital
<i>Comparative Effectiveness of Multimodal Interventions to Prevent Osteoporotic Fractures</i>	
Effectiveness of a Multimodal Intervention for Transitions of Care After Lower Limb Fracture	Brigham and Women's Hospital
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA	Institution
The TRIAD (Treatment Individualized Appendicitis Decision-making) Implementation Program	University of Washington
Technology-Assisted Implementation of a Mobile Health Intervention for Serious Mental Illness	University of Washington

Today's Awards in Context of FY 2022 Commitment Plan

Award Category	FY 2022 Commitment Target for Award Category	FY 2022 Cumulative Commitments with These Additions
Research	\$500M	\$380M
Dissemination & Implementation	\$40M	\$16M

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* All project budgets proposed by awardees are subject to programmatic and budget approval by PCORI staff and the negotiation of a formal award contract.

FY 2022 Mid-Year Financial Results

(October 1, 2021 – March 31, 2022)

Russell Howerton

Chair, Finance and Administration Committee
(FAC)

Brian Trent, MPA

Deputy Executive Director, Operations

The Bottom Line and What's Next



- ***Budget for FY 2022 on target at mid-year***, despite uncertainty resulting from pandemic
- ***Budget Development for FY 2023*** – Board considers in September
- ***Commitment Planning for FY 2023 forward*** – Board considers in December

FY 2022 Revenue

(10/1/2021 – 3/31/2022)



REVENUE	<i>\$ in millions</i>
From PCOR Trust Fund	
Federal Appropriation	\$ 234.8
PCOR Fee	-
PCOR Fee True-Up	(3.9)
From Interest (U.S. Treasury Securities)	0.9
Total Revenue	\$ 231.8

Cash Balance and Outstanding Award Obligations

(As of 3/31/2022)



CASH BALANCE		<i>\$ in millions</i>
Cash -- PCOR Trust Fund	\$	13.4
Cash -- Operating Account		36.9
U.S. Treasury Securities		1,562.9
Total Cash Balance		1,613.2
OUTSTANDING AWARD OBLIGATIONS		<i>\$ in millions</i>
Cumulative Funding Commitments		3,477.7
Cumulative Award Payments		(2,255.2)
Total Outstanding Award Obligations		1,222.5
Unobligated Cash Available	\$	390.7

FY 2022 Actual Expenses vs. Budget

(October 1, 2021 – March 31, 2022)



	FY 2022 YTD ACTUAL		FY 2022 YTD BUDGET		FY 2022 YTD VARIANCE	
	\$ in millions					
REVENUE	\$	231.8		\$	234.9	\$ (3.1) (1)%
EXPENSES						
PROGRAM SERVICES						
Award Payments		139.2	77%	150.6	78%	11.4 8%
Programs & Program Operations		27.2	15%	27.6	14%	0.4 1%
TOTAL PROGRAM SERVICES		166.4	92%	178.2	92%	11.8 7%
ADMINISTRATIVE SUPPORT		15.3	8%	15.9	8%	0.6 4%
TOTAL EXPENSES	\$	181.7	100%	\$	194.1	100%
	\$					\$ 12.4 6%

Closing Remarks

Nakela L. Cook, MD, MPH
Executive Director

Wrap Up and Adjournment



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