# Increasing Vaccine Confidence among Long-Term Care Workers (LTC): Expedited COVID-19 Targeted PFA

**Applicant Town Hall**
**April 19, 2021**

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# Agenda

- **About PCORI**
- **Programmatic Overview**
- **Patient and Stakeholder Engagement**
- **Administrative Overview**
- **Merit Review Process**
- **Resources**
- **Questions and Answers**

 Submit questions via the Question box in GoToWebinar

# Today's Presenters



**Jason Gerson**
Senior Program Officer
Clinical Effectiveness &
Decision Science



**Julie Kennedy Lesch**
Senior Engagement Officer
Public & Patient Engagement



**Michele Lee Clements**
Contract Administrator
Contract Management



**Carolyn Mohan**
Assistant Director
Merit Review

# Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from **research guided by patients, caregivers and the broader health care community.**

# Focus on Comparative Clinical Effectiveness Research (CER)

**CER includes:**

- Studies that compare health outcomes and the clinical effectiveness, risks, and benefits of two or more approaches to healthcare
  - Clinical effectiveness research
  - Improving healthcare delivery CER
  - Communications and dissemination CER
  - CER to reduce/eliminate health and healthcare disparities

# Research We Do <u>Not</u> Fund

PCORI does not fund studies of cost-effectiveness analysis (CEA).

### Examples of CEA

- Research that conducts a formal CEA in the form of dollar-cost per quality-adjusted life-year (including non-adjusted life-years) to compare two or more alternatives

- Research that directly compares the overall costs of care between two or more alternative approaches as the criterion for choosing the preferred alternative

# Research We Do <u>Not</u> Fund

**PCORI does not fund research whose findings will include**

- Development of clinical practice guidelines
- Coverage or payment recommendations

**NOTE:** PCORI does fund studies that explore the burden of costs on patients—for example, out-of-pocket costs.

# PFA Overview

# PCORI Priority: Healthcare workforce well-being

pcori

- Pre-specified, narrow research question: **What interventions are effective in increasing COVID-19 vaccine confidence and uptake among LTC workers?**
  - LTC includes a diverse range of settings and types of workers
- Pre-specified, required primary outcomes**: COVID-19 vaccine uptake** and/or **vaccine series completion**
  - Secondary outcomes listed in PFA – we encourage parsimony in selection!
- Additional questions of interest:
  - Which interventions are most effective in increasing vaccine confidence and uptake among LTC workers who experience health disparities?
  - How can evidence be integrated into vaccine promotion interventions to identify/address misinformation regarding vaccination?

# Important study considerations

- Potential study designs
  - Interventional study designs (e.g., a parallel group or cluster-randomized trial, an individually randomized group treatment trial, a stepped-wedge design)
  - Observational designs (including natural experiments)
  - Hybrid designs
- Disproportionately affected populations of LTC workers experiencing health disparities
- Efficacy and adaptation of existing interventions
- Potential collaborations
- Ability to initiate and implement study rapidly
- Generating timely results

# Funding Mechanism Overview

pcori

- This funding announcement has an **accelerated funding and results-generating timeline** to support innovative, high-impact studies
  - Consists of a two-stage review process with an expedited timeline
- Following application submission, all applications will be evaluated through a programmatic screening process
  - Only select applications deemed most responsive will be invited to an Applicant Consultation meeting, **a stage required to be considered for funding**.
- Applicants will be notified on May 17, 2021 whether they will participate in an Applicant Consultation meeting
  - Invitation will include instructions on what will be required in preparation for meeting

# Applicant Consultation (AC) Meeting and Funding Decisions

- For this expedited PFA, PCORI staff and external reviewers will serve as review panel

- **Purpose of this meeting is to invite the applicant study team (PI, AO, and up to 1 additional person) to communicate directly with review panel to address programmatic and administrative questions of proposed research**

- AC will focus on one application per meeting and are expected to last no more than 4 hours

  - AC meetings will take place between June 7 and 16

- Post AC, PCORI program staff will review final scores and comments to make funding recommendations to our Selection Committee and Executive Director

- Applicants that participate in an AC meeting will receive notification of the funding status in **July 2021**

# Patient and Stakeholder Engagement

# Patients and Other Stakeholders



PCORI Community

- Patient/Consumer
- Caregiver/Family Member of Patient
- Clinician
- Patient/Caregiver Advocacy Org
- Hospital/Health System
- Training Institution
- Policy Maker
- Industry
- Payer
- Purchaser

Definitions can be found here: https://www.pcori.org/about-us/our-programs/engagement/public-and-patient-engagement/pcoris-stakeholders

# Patient-Centeredness vs. Patient Engagement

- **Patient-Centeredness**
  - Addresses outcomes (both benefits and harms) that are important to patients
  - The interventions proposed for comparison are currently available to patients
  - Study design is low-burden to participants

- **Patient and Stakeholder Engagement**
  - Patients and stakeholders are partners in research, not only "subjects"
  - Leverages the expertise of patients, clinicians and other stakeholders for the purpose of improving study design and conduct
  - Includes a range of engagement approaches: input, consultation, collaboration, shared leadership
  - Can occur by building upon existing relationships, or developing new ones

# "Research Done Differently"

PCORI's research has shown that engagement can impact studies:

**Acceptability:** studies in which patients and clinicians will be willing to participate based on burden, usability, and alignment with preferences, values, and needs
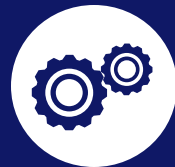
**Feasibility:** mitigating potential or actual roadblocks—particularly to making interventions, enrollment, retention, and data collection more doable in real-world settings

**Rigor:** choices that minimize bias and enhance data quality

**Relevance:** applicability and importance of the research for patients and clinicians making decisions, including the importance of research questions and outcomes, generalizable study samples, interpretations of findings in a real-world context, and more effective dissemination

Forsythe LP, Carman KL, et al. Patient Engagement In Research: Early Findings From The Patient-Centered Outcomes Research Institute. Health Aff (Millwood). 2019 Mar;38(3):359-367;

# Administrative Requirements

# Using the PCORI Online System

- Register as a New User as soon as possible

- Please note that the PI and AO cannot be the same person

- Please only use **Chrome, Safari, and Firefox browsers** to access the system

https://pcori.force.com/engagement
PCORI Online Training Slides
PCORI Online Application Cheat Sheet
PCORI Online Training Resources

# Eligibility to Apply

- Any private sector (non-profit or for-profit) research organization.

- Any public sector research organization (university or college hospital or healthcare system, laboratory or manufacturer, unit of local, state, or federal government).

- Non-domestic components of organizations based in the US and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown.

- Individuals are not permitted to apply.

# Invited to Apply: Tips for Success

- Adhere to the Submission Instructions for the appropriate PFA and funding cycle

- Start and submit application early

- Ensure that all team members can see the application in the system

- Inform your AO of your intent to submit

- Clearly describe comparators for the study

- Submit the completed application on/before the due date by **5:00 PM ET**

# Application Components: Research Plan

- **Research Strategy: 6 pages**
  - Provide all the information requested, as outlined in the template:

    *Research Question/Specific Aims     *Significance

    *Study Design or Approach *Recruitment and Participant Information for Prospective Studies

- **Research Team & Environment: 2 pages**
  - Describe the research team's capabilities to accomplish the goals of the proposed research project and the appropriateness of the research environment to conduct the study.

- **Dissemination & Implementation: 1 page**
  - Describe how you will make study results available to study participants after you complete the analyses, and possible barriers to disseminating and implementing the results of this research in other settings.

- **Return of Aggregate Study Results: ½ page**

  - Describe the approach that will be used to communicate the research findings to study participants once the study is complete.

- **Protection of Human Subjects: 3 pages**
  - PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule.

# Application Components: Research Plan (cont.)

pcori

- **References Cited:  5 pages**

  - List the full bibliographical citation for each reference. Each reference must include the names of all authors the article title and journal or book title, the volume number, the page numbers, and the year of publication

- **Appendices: 5 pages (optional)**

  - Applicants can include additional materials that they believe are useful, but reviewers are <u>not</u> required to review the appendix materials in evaluating the application.

# Additional Application Components

- **Budget Materials Template**
  - Budget Summary (Section 1)
  - Budget Justification (Section 2)

- **PI Template**
  - Professional Profile Biosketch (5 pages per individual)
  - Patient/Stakeholder Partner Profile/Biosketch (5 pages per individual)

# Application Consultation Checklist Requirements

**If invited to participate in a virtual Application Consultation, the following materials must be submitted to PCORI.**

- *Although these materials are not required during the application submission process, templates are provided in the PCORI Funding Center so that applicants may prepare these materials in advance*

- **Standard questions for Applicant Consultation Template** (5 pages)

- **Milestones Template:** no page limit

- **Key Personnel Template**
  - Professional Profile/Biosketch (5 pages per individual)
  - Patient/Stakeholder Partner Profile/Biosketch (5 pages per individual)

- **Letters of Support:** no page limit

- **Detailed Budget Template:** no page limit, Excel file

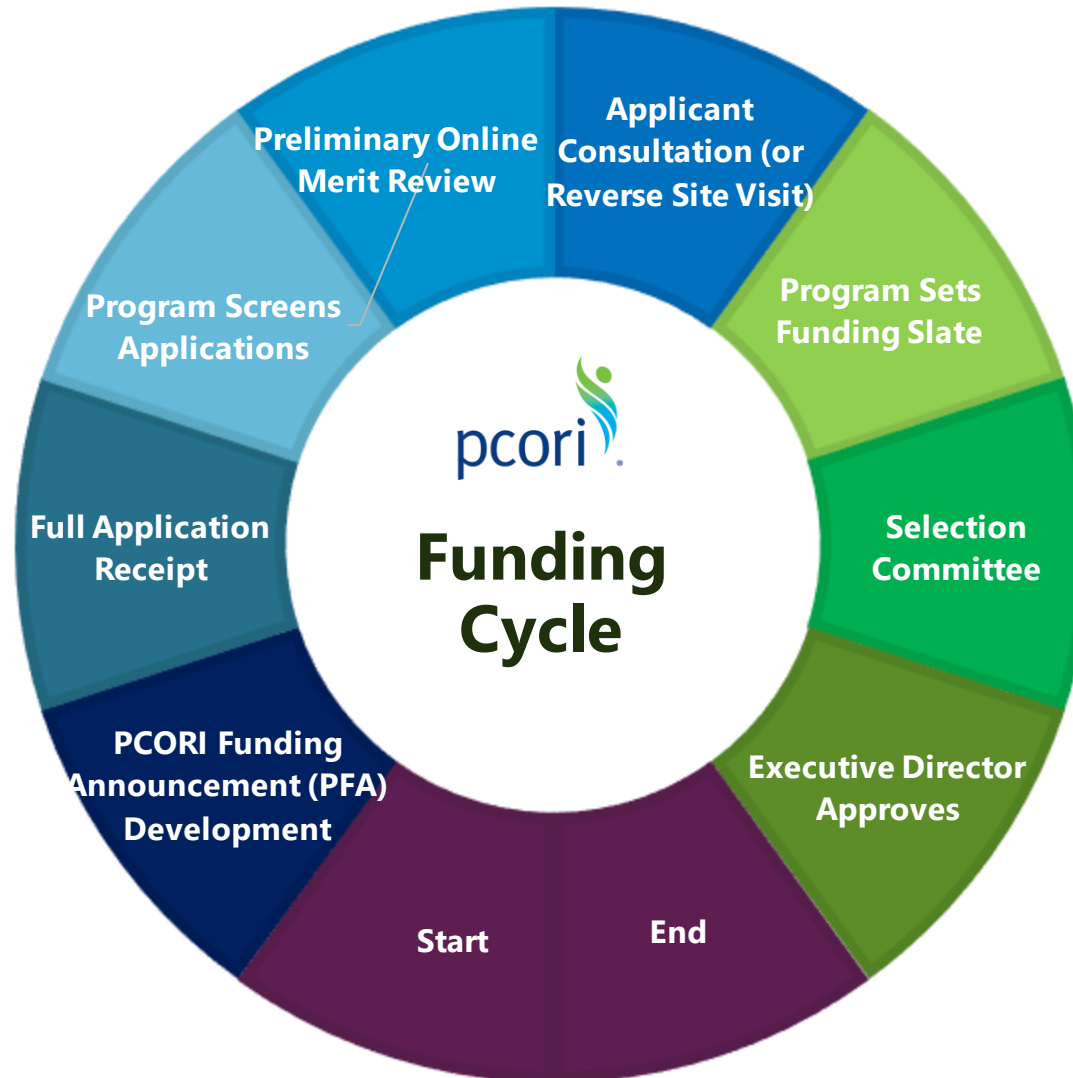# Additional Components if selected for funding

- **If selected for funding, the following materials will be required.**
  - *Although these materials are not required during the application submission process, templates are provided in the PCORI Funding center so that applicants can prepare these materials in advance.*

- **Methodology Standards Checklist:**
  - Applicants must complete each column of this checklist, as appropriate

- **Budget Materials**
  - Federally negotiated or independently audited Indirect Cost Rate Letter
  - Fringe Benefit Rate Policy Verification Document (Prime)

# Merit Review

# Merit Review Process

# Application Review

**Applications are reviewed against six criteria:**

1. Potential to address an important and compelling clinical or care delivery question raised by COVID-19
2. Potential for the study to generate actionable findings to inform clinical practice and/or public health responses, decision making and planning.
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

# Submission and Key Dates

| What | Deadlines |
|---|---|
| Application Deadline | May 4, 2021 by 5 PM ET |
| Applicant Consultation Materials Deadline (if invited) | June 1, 2021 by 5 PM ET |
| Applicant Consultation/PCORI Review Panel (invite only) | June 7 – 16, 2021 |
| Awards Announced | July 2021 |
| Earliest Start Date | August 2021 |

# Resources

**Refer to the funding opportunities page in our Funding Center for the following resources:** https://www.pcori.org/funding-opportunities

- PFA and Submission Instructions

- General Applicant FAQs: https://help.pcori.org/hc/en-us/categories/200010230-Applicant-Resources

- PCORI Methodology Standards: https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards

- PCORI Online: https://pcori.force.com/engagement/

- PCORI Online User Manuals: https://www.pcori.org/sites/default/files/PCORI-Online-User-Access-Cheat-Sheet.pdf

- Blog Post: PCORI Improves Funding Opportunities and Application Process for 2021: https://www.pcori.org/blog/pcori-improves-funding-opportunities-and-application-process-2021

# Specific Engagement Resources

Please visit PCORI's website for updated content and resources on the Public and Patient Engagement pages: [https://www.pcori.org/engagement/engagement-resources](https://www.pcori.org/engagement/engagement-resources)

- The value of engagement and planning for effective engagement in research
- Definitions and examples of different stakeholders
- Engagement Resources
  - Engagement Rubric
  - Compensation Framework
  - PCORI in Practice webinars
  - Research Fundamentals training for lay person partners
- [Engagement in Health Research Literature Explorer](#)

# Where can I find help?



**Quick Links for Applicants**

Key Terms Glossary

Frequently Asked Questions (FAQs)

PCORI Online User Manual: Start a LOI

PCORI Online User Manual: Submitting an Application

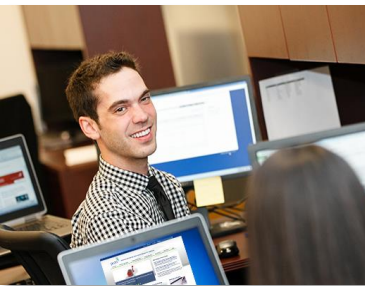PCORI Funded Projects: Sample Engagement Plans
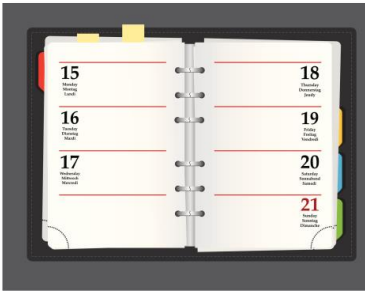




**Visit pcori.org/apply**
- Submission Instructions
- FAQs
- PCORI Online User Manuals
- Sample Engagement Plans

**Schedule a Call with a Program Officer**
- Submit a request at pcori.org/content/research-inquiry
- Call 202-627-1884 (programmatic inquiries)
- E-mail sciencequestions@pcori.org

**Contact our Helpdesk**
- E-mail pfa@pcori.org
- Call 202-627-1885 (administrative and technical inquiries)

# Q&A

**Ask a question via the question box in GoToWebinar**

*If we are unable to address your question during this time, e-mail the Helpdesk at [pfa@pcori.org.](mailto:pfa@pcori.org)*

# Thank you