Cycle 2 2021 Funding Cycle

Expedited Targeted PCORI Funding Announcement: *Increasing COVID-19 Vaccine Confidence among Long-Term Care Workers*

Published April 13, 2021

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes May 4, 2021, at 5 pm (ET). Submission Instructions, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/increasing-vaccine-confidence-among-long-term-care-workers-expedited-covid-19-tPFA-april-2021.
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 and reauthorized for an additional ten years in 2019, as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by its authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions” and by promoting the dissemination and uptake of this evidence.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information generated through research guided by patients and other stakeholders.
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<th>Key Dates</th>
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<td>Town Hall: April 19, 2021, 12 pm ET</td>
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<td>Application Deadline: May 4, 2021, by 5 pm (ET)</td>
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<td>Application Status Notification: May 17, 2021</td>
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<td>Applicant Consultation Materials Deadline: June 1, 2021</td>
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<td>Applicant Consultation Meeting: Between June 7 – June 16, 2021</td>
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<td>Awards Announced: July 2021</td>
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<td>Project Start Date: August 2021</td>
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<th>Maximum Project Budget (Direct Costs)</th>
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<td>Maximum Research Project Period</td>
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<td>Funds Available Up To</td>
<td>$28 Million</td>
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| Contact Us                             | Programmatic Inquiries: sciencequestions@pcori.org, phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). |
|                                       | Administrative, Financial, or Technical Inquiries: pfa@pcori.org or phone (202-627-1885). |

PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to application deadline. Applicants must plan accordingly; it is the applicant’s responsibility to submit on time.
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Introduction

PCORI was created to improve the evidence about what works in health care, to better inform real, specific choices faced by patients, caregivers, clinicians, healthcare administrators, and others in the healthcare community. The COVID-19 pandemic has taken a terrible toll on communities across the country and brought with it unprecedented challenges to the US healthcare system. As of April 2021, the pandemic has resulted in more than 30,000,000 cases and over half a million deaths in the United States alone.\(^1\) Moreover, the pandemic has disproportionately impacted communities of color; racial, ethnic, or sexual and gender groups; and those of lower socioeconomic status; among others. Early in the pandemic, long-term care (LTC) facilities were epicenters of COVID-19 outbreaks, accounting for a large share of COVID-19-related deaths.\(^2\)

Although the availability of several efficacious COVID-19 vaccines offers the promise of ending the pandemic, that outcome depends on widespread uptake of the vaccine. A key determinant of uptake is vaccine confidence: the trust that patients, families, and healthcare workers have in authorized vaccines; those who administer vaccines; and processes and policies that lead to vaccine development, authorization, manufacturing, and recommendations for use. Widespread vaccine acceptance hinges on building confidence and trust through transparent, culturally responsive communication that provides balanced and accurate information on vaccination benefits and risks.

Low vaccination coverage among individuals working in LTC settings was described in a February 2021 Centers for Disease Control and Prevention report and recounted widely in the media.\(^3\) LTC settings include nursing facility care, adult day programs, retirement communities, post-acute rehab centers, assisted living facilities, and community-based services. Although efforts to promote confidence in COVID-19 vaccination among LTC workers are ongoing, a November 2020 survey found that only 45 percent of respondents were willing to receive a COVID-19 vaccine immediately once available and an additional 24 percent would consider it in the future.\(^4\) Frequently cited reasons for lack of vaccine confidence included the perceived rapidity of vaccine development; inadequate information received

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about vaccine safety, side effects, and administration; and skepticism regarding the clinical trials and vaccine authorization processes.

Per an April 2020 Kaiser Family Foundation report, the LTC workforce consists of a variety of occupations and workers with different levels of direct day-to-day patient contact, but most of the 4.5 million LTC workers are in close, frequent contact with patients. The vast majority of the LTC workforce is female (82 percent). Nearly half of aides and personal care workers are Black or Latinx (32 percent and 16 percent, respectively), and approximately one in four direct-care workers in LTC settings was born in a foreign country. LTC workers overall are also disproportionately lower-wage earners and have less formal education. About one-third live in a family with income below 200 percent of the federal poverty level, and nearly 40 percent have a high school diploma or less.

Increasing vaccine confidence and uptake among LTC workers requires consideration of these demographic, cultural, and socioeconomic factors. In addition, interventions need to take into account the structural challenges of LTC settings, including long-standing personnel shortages, high turnover, individuals working in multiple settings, and limited resources for worker outreach and education. Increasing confidence and uptake among LTC workers is critical to protecting the workers themselves; other workers with whom they come into contact; the patients and families they serve; and the loved ones, friends, and neighbors in the communities where they reside.

In the COVID-19 Targeted PFA released in May 2020, PCORI made healthcare workforce well-being a key priority. In keeping with this priority, PCORI is issuing a new research funding announcement with an accelerated funding and results-generating timeline to support innovative, high-impact studies that fit clearly within PCORI’s core mission of patient-engaged and patient-centered comparative clinical effectiveness research.

Research Question
For this funding opportunity, PCORI encourages applicants to address the following question: What interventions are effective in increasing COVID-19 vaccine confidence and uptake among LTC workers?

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Interventions include, but are not limited to, the following (please note that interventions may be combined):

- Educational, communication, and behavioral economics strategies, tools, or approaches
- System- or organizational-level responses
- Digital marketing (e.g., social media, mobile) and other innovative technologies
- Single- versus two-dose vaccines
- Culturally specific and/or community competent approaches for reducing barriers

Additional questions that may be addressed for relevant subpopulations, settings, and interventions may include the following:

- What interventions and strategies are most effective to increase the acceptance of vaccines among populations of LTC workers who experience health disparities?
- How can evidence be integrated into vaccine promotion interventions to identify and address the sources of misinformation regarding vaccination?

**Exclusive primary outcomes:** COVID-19 vaccine uptake and/or vaccine series completion

**Note:** For this PFA, selection of either or both of the primary outcomes listed above is required. No other primary outcomes may be selected. If other primary outcomes are included in the application, the application will be deemed nonresponsive to this funding announcement.

**Secondary outcomes (may include as appropriate, but are not limited to the following):** COVID-19 vaccine confidence and vaccine hesitancy; community/social vaccine beliefs, misconceptions, misinformation, norms, and risk perceptions; adherence to COVID-19 vaccine protocols; COVID-19 vaccine distribution and implementation across various sectors/settings; implementation of policies to increase individual access and uptake; access to immunization services; service delivery improvements; trust in science supporting COVID-19 vaccine research; trust in government and health organizations providing COVID-19 vaccine recommendations; anxiety and stigma; and employment-related outcomes (e.g., lost days from work, continuity of the workforce, employee turnover)

**Note:** The inclusion of many secondary outcomes is generally discouraged. Secondary outcomes are typically used to assess additional effects after positive results are evident on the primary outcomes. If an outcome is merely for exploratory purposes, such outcomes should be so classified.

**Important Study Considerations**

**Study design:** PCORI encourages the use of diverse methods, including interventional study designs (e.g., a parallel group or cluster-randomized trial, an individually randomized group treatment trial, a stepped-wedge design) and observational designs (including natural experiments), to conduct
research on an accelerated timeline. Hybrid designs, which can provide insight into implementation approaches in the context of evidence generation, will also be considered.

**Disproportionately affected populations of LTC workers and health disparities:** Given the diverse populations that compose the LTC workforce, research that seeks to understand what interventions are most effective for specific subgroups is desirable. Specific subgroups of interest include workers from communities of color; racial, ethnic, or sexual and gender groups; workers of lower socioeconomic status; and workers who experience health disparities. In addition, applications that seek to understand effective interventions for those workers exposed to misinformation about vaccinations is encouraged.

**Efficacy and adaptation of existing interventions:** PCORI is willing to consider studies that include comparators for which efficacy evidence has been generated in non-COVID contexts. We encourage the thoughtful adaptation of interventions currently in use to increase uptake of other vaccinations, including how to best tailor these interventions to workers of diverse racial, ethnic, and socioeconomic backgrounds or who have low health literacy.

**Generating timely results:** In considering the timeline and scope of their proposed study, applicants should bear in mind the importance of generating timely, relevant information for addressing the pandemic. PCORI strongly encourages applications that demonstrate readiness to produce preliminary results/outcomes **within the first 12 months of the proposed study.**

**Potential collaborations:** Applications may benefit from collaboration between researchers with expertise working in LTC settings and researchers with expertise in behavioral research concerning vaccine uptake. Applicants should demonstrate that members of their proposed study teams have expertise in these areas. Within the context of the COVID-19 pandemic, PCORI recognizes that forming and sustaining such relationships may be challenging and encourages the use of creative and flexible approaches that facilitate collaboration.

**Funds Available and Duration of Studies**
PCORI has allotted up to $28 million under this PFA to fund high-quality comparative clinical effectiveness studies that are responsive to the research question of interest. The proposed budget for studies under this initiative may be up to $5 million in direct costs, as appropriate.

Although the maximum allowable project period is three years (36 months), studies with rigorous, well-justified design and analysis plans that may be completed in a two-year or shorter timeframe are preferred. In particular, those studies that can report on primary outcomes of vaccine uptake and/or vaccine series completions within 12 months are strongly encouraged, if feasible.
General Requirements for PCORI-Funded Research

This section includes language that is specific to PCORI’s requirements for programmatic responsiveness under this funding announcement. Applicants should use this section as guidance when preparing their applications. For information related to administrative and technical requirements for application submission, please consult the PCORI Submission Instructions.

Research Priorities

To be considered responsive, applications must:

- **Describe comparators.** Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. If the applicant proposes “usual care” as a rational and important comparator in the proposed study, then it must be described in detail, coherent as a clinical alternative, and properly justified as a legitimate comparator (e.g., “usual care” is guidelines-based). It must also be accompanied by an explanation of how the care given in the “usual care” group will be measured in each patient, and how appropriate inferences will be drawn from its inclusion. “Usual care” must be described as mentioned above to ensure that it accounts for geographic and temporal variations, and it has wide interpretability, applicability, and reproducibility.

- **Describe research that compares two or more alternatives, each of which has established efficacy.** PCORI encourages the comparison of interventions that are used widely or have established efficacy or effectiveness but is willing to consider studies that include comparators for which efficacy evidence has been generated in non-COVID contexts and encourage the thoughtful adaptation of interventions used to increase uptake of other vaccinations. The application should provide information about the efficacy or effectiveness of interventions that will be compared; pilot data might be appropriate. Projects aiming to develop new interventions that lack evidence of efficacy or effectiveness entirely, will be considered out of scope.

- **Describe research that studies the benefits and harms of interventions and strategies delivered in real-world settings.** PCORI is interested in studies that provide practical information that can help stakeholders make informed decisions about their healthcare and health outcomes.

- **Describe consultation with other stakeholders about how the study is answering a critical comparative question.** Explain the pertinent evidence gaps about the proposed comparison and why the project questions represent decisional dilemmas for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders. Describe why project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.
Categories of Non-responsiveness

PCORI discourages proposals in the following categories, and will deem them nonresponsive:

- Instrument development, such as new surveys, scales, etc.
- Developing, testing, and validating new decision aids and tools, or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Comparing patient characteristics rather than clinical strategy options

Consistent with PCORI’s authorizing law, PCORI does not fund research whose findings will include:

- Coverage recommendations
- Payment or policy recommendations
- Creation of clinical practice guidelines or clinical pathways
- Establishment of efficacy for a new clinical strategy
- Pharmacodynamics
- Study of the natural history of disease
- Basic science or the study of biological mechanisms

Principles for Consideration of Full Range of Outcomes Data in PCORI Funded Research

PCORI’s authorizing law was amended by reauthorization legislation in 2019 to include a new mandate to consider, as appropriate, the full range of clinical and patient-centered outcomes data relevant to patients and stakeholders. The reauthorizing language clarifies that in addition to the relevant health outcomes and clinical effectiveness, relevant outcomes included within PCORI-funded projects may include the potential cost burdens and economic impacts of the utilization of medical treatments, items, and services when relevant to patients and caregivers or to other stakeholders. The parameters for appropriately including such outcomes are further described below and in the accompanying FAQs. PCORI’s intention is that PCORI-funded research will, when germane, capture such cost burdens and economic impacts to provide the full range of outcomes data relevant to decision makers.

Specifically, applications responding to this PFA may include the following:

- Data collection on cost burdens or economic impacts associated with interventions that are relevant to patients and caregivers. Examples of elements of cost burden and economic impacts important to patients and caregivers include patient’s time in hospital, caregiver time away from work, cost and time for transport, childcare and eldercare costs, and medical out-of-pocket costs.
- Data collection on cost burdens and economic impacts relevant to other stakeholders, when these outcomes have a near-term or longer-term impact on patients, such as cost of treatment/intervention, costs associated with impacts of treatment on healthcare utilization, costs of a new intervention (program costs), and employer burden.

8 Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf/.
PCORI-funded studies have often included impacts of healthcare utilization, and data that capture the costs of these impacts will now be considered responsive. However, proposed research may not measure economic impacts as the primary outcome of a proposed study. Proposals that have economic measures as the primary outcome will be considered non-responsive.

Further, consistent with past funding announcements, PCORI will consider an application nonresponsive if the proposed research does the following:

- Conducts a formal cost-effectiveness analysis of alternative approaches to providing care
- Directly compares the costs of care between two or more alternative approaches to providing care, or relies on modeling to develop estimates of “total costs of care” designed to enable such comparisons.

For further information, please reference our cost-effectiveness analysis FAQs.

PCORI has a continued interest in studies addressing questions about conditions that lead to high costs to individuals or society. This interest is reflected in our review criterion on the condition’s impact on the health of individuals and populations. Thus, as addressed in the cost effectiveness analysis FAQs, PCORI is interested in studies that:

- Examine the effect of costs on patients, such as patients’ out-of-pocket costs, hardship, or lost opportunity, or costs as a determinant of, or barrier to, access to care
- Address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention.
- Evaluate interventions to reduce health system waste or increase health system efficiency.

In March 2021, PCORI’s Board of Governors approved Principles for the Consideration of the Full Range of Outcomes. These Principles will inform both PCORI’s expectations for applicants and the corresponding review evaluation of applications submitted in response to this PFA.

Coverage of Intervention Costs
In general, PCORI will not cover costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that are being proposed for comparison in the research project (“patient care costs”).

Avoiding Redundancy
PCORI encourages potential applicants to review funded research at pcori.org. We intend to balance our funded portfolio to achieve synergy and avoid redundancy where possible.

Methodological Considerations
The PCORI Methodology Standards represent minimal requirements for the design, conduct, analysis,
and reporting of scientifically valid, patient-centered outcomes research. Regardless of study design, applications must adhere to all relevant PCORI Methodology Standards, and all deviations need to be justified. Applicants should address additional best practices—including relevant guidelines for conducting clinical trials developed by other organizations. **If funded, awardees must complete a Methodology Standards Checklist to be submitted with their study protocol.**

**Patient-Centered Outcome Measures**

PCORI encourages investigators to design their research using validated outcome measures. Include within the application preliminary data that support using the proposed measures in the study population. We encourage investigators to consider those measures described in the **Patient-Reported Outcomes Measurement Information System** (PROMIS). Likewise, PCORI encourages the use of core outcome sets, such as those developed by the Core Outcomes Measures in Effectiveness Trials Initiative to facilitate cross-study analysis. See [http://www.comet-initiative.org/](http://www.comet-initiative.org/).

**Patient and Stakeholder Engagement**

In PCORI-funded research, patients, caregivers, clinicians, and other healthcare stakeholders are viewed as partners who leverage their lived experience and/or professional expertise to influence research to be more patient centered, relevant, and useful. PCORI encourages applicants to consider the time and resources needed to identify, confirm, and prepare stakeholders for collaborating; the infrastructure needed to manage stakeholder engagement activities; and the specific decision points that will draw on stakeholder partners’ expertise. Research partners must include representatives of the populations most impacted by the condition or issue addressed by the study. Applicants’ use of multiple approaches that are along a continuum of engagement from input to shared leadership are allowable and encouraged.10

Within the context of the COVID-19 pandemic, PCORI recognizes that forming and sustain conventional partnerships may be challenging, so it encourages the use of novel, creative, and flexible engagement approaches that facilitate the inclusion of stakeholder perspectives in key decisions that may influence study design, conduct, and dissemination of findings. Examples of such approaches include rapid structured methods (e.g., surveys, virtual community forums) to gather input from members of stakeholder groups quickly, in addition to engaging stakeholders via ongoing consultative groups (e.g., advisory committees, working groups), collaborative arrangements, and leadership positions (e.g., co-investigators, multidisciplinary steering committees) that are sustained over the course of the study. PCORI recognizes that plans for engagement with stakeholders may be evolving, so applicants should submit their most current ideas for identifying and soliciting input from representatives of stakeholder groups most affected by COVID-19 and for the decision points for which they will be consulted.

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Applicants are required to briefly identify the patient and other stakeholder partners (individuals or organizations) who will be engaged, provide the rationale for their inclusion, and provide a summary of engagement activities. If funded, awardees must submit a detailed engagement plan two months after contract execution.

**Populations Studied and Recruited**

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations. PCORI recognizes that some proposed studies might represent important PCOR opportunities, even in the absence of a broadly diverse study population. However, the burden is on the applicant to justify the study’s importance in the absence of diversity; to discuss which subgroups are most important and posit the hypotheses regarding the subgroups; and to discuss how the subgroups will be analyzed, including whether or not the study will be powered to examine the question of effectiveness in subgroups.

PCORI is particularly interested in including previously understudied populations for whom effectiveness information is especially needed, such as hard-to-reach populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibility that the strategy’s effects might differ across subpopulations. PCORI has developed the following list of populations of interest to guide our efforts in research and engagement.

- Racial and ethnic minority groups
- Low-income groups
- Women
- Older adults (age 65 years and older)
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities
- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic makeup affects their medical outcomes
- Individuals with low health literacy, numeracy, or limited English proficiency
- Gender and sexual minorities
- Veterans and members of the Armed Forces and their families

Regardless of the population studied, investigators are expected to provide evidence-based estimates regarding the representativeness of the potential pool of participants from which recruitment will occur; the target sample size; and recruitment and retention rates, reflecting the study’s inclusion and exclusion criteria as well as factors that may impact the final sample size (e.g., loss to follow-up).
Protection of Human Subjects

PCORI follows the Federal Regulations for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, titled “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which is issued by the U.S. Department of Health and Human Services (HHS). In referencing the HHS Supplemental Grant Application Instructions, note that PCORI does not require that applicants comply with sections of that policy that refer to requirements for federal-wide assurance and the inclusion of women, minorities, and children in the proposed studies. Instead, PCORI expects applicants to address diversity in study participants in the research plan, through a focus on subpopulations, as described in the above section on Populations Studied and Recruited. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include the need to appoint a Data and Safety Monitoring Board, as provided in the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research. If funded, awardees must provide a Data and Safety Monitoring Plan within the first four months of the study.

The PCORI Review Panel will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see How To Evaluate Human Subjects Protections). Reviewers’ comments on human subject research are not reflected in the overall application score, but PCORI staff might use them during potential funding negotiations. Final determinations about the adequacy of human subject protections rest with the Institutional Review Board or international equivalent that have jurisdiction for the study.

The Awardee Institution, whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

Required Education of Key Personnel on the Protection of Human Subject Participants

PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel. The policy and FAQs are available on the NIH website.

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Programmatic Screening

Applying for funding from PCORI for this PFA is a two-stage process with an expedited timeline. Following application submission, all applications will be evaluated through a programmatic screening process. **Only select applications will be invited to an Applicant Consultation.** Refer to the Submission Instructions for more details on the application process and required materials. Due to the expedited timeline of this funding opportunity, PCORI encourages all applicants to review all templates and materials ahead of application submission.

Note that PCORI may eliminate applications from the review process for administrative or scientific reasons (e.g., nonresponsiveness). An application may be withdrawn if it is incomplete; submitted past the stated due date and time; or does not adhere to the formatting criteria outlined in the Submission Instructions, in the PCORI templates, and in PCORI Online. An application may be withdrawn if it is not responsive to the guidelines described in this PFA, describes research that is not comparative, includes a cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

Applications will be evaluated based on the following:

- Does the application adhere to administrative requirements specified in the PFA?
- Does the application address the research question, interventions, outcomes, and settings specified in the PFA?
- Does the proposed study demonstrate readiness to generate preliminary results/outcomes within the first 12 months of the study (e.g., existing partnerships or collaborations, recent publication track record in the areas of vaccine uptake and/or research in LTC settings, access to and readiness of proposed data)?
- At the completion of the study, will there be actionable findings that could be implemented immediately?
- Does the applicant propose an appropriate and sound approach to address the research question?
- Does the study have appropriate partnerships and adequate infrastructure to (a) ensure timely commencement and completion, and (b) support downstream uptake of the findings?

PCORI staff will screen all applications. Only applicants whose applications are deemed most responsive to this PFA will be invited to participate in a virtual Applicant Consultation meeting with the PCORI Review Panel, a stage required to be considered for funding. Applicants will be notified of their invitation to an Applicant Consultation meeting on May 17, 2021.
Merit Review

PCORI’s merit review process is designed to support the following goals:

- Identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes.
- Implement a fair, transparent, objective, and consistent process to identify these applications.
- Elicit high-quality feedback that reflects a diversity of perspectives to ensure that PCORI-funded research meets the criteria for scientific rigor and reflects the interests and views of patients, caregivers, and other stakeholders.
- Identify projects that fill important evidence gaps and have strong implementation potential.
- Regularly evaluate and continually improve the merit review process and policies in support of PCORI’s mission.

Applicant Consultation

For this expedited PFA, PCORI staff and external reviewers who are subject matter and/or methodology experts will serve on the PCORI Review Panel. PCORI recruits external reviewers based on their experience with the topic areas relevant to the targeted PFA. All panel members receive training to ensure that they understand the programmatic and organizational priorities for the funding opportunity.

Following application submission and programmatic screening, applicants will be notified on May 17, 2021, as to whether their application has advanced to the second stage of review, which includes participation in a virtual Applicant Consultation. The invitation will also include instructions on how to submit to PCORI all additional documents requested at the time of the Applicant Consultation invitation. The purpose of the Applicant Consultation meeting is to invite the applicant study team (Principal Investigator (PI), Administrative Official (AO)), and up to one additional representative) to communicate directly with the PCORI Review Panel to provide further information about the application and address programmatic and administrative questions about the proposed research. Applicant Consultations will focus on one application and are expected to last no more than four hours. Invitees will be provided with a common agenda framework for the discussion. It is expected that all Applicant Consultations will take place between June 7 and 16, 2021. To be considered for funding, applicant study teams must be available to participate during this period.

Applicants invited to participate in an Applicant Consultation will receive a set of standard questions that will be emailed to the PI and AO before the meeting; written responses and any other requested deliverables must be submitted ahead of the Applicant Consultation. These questions, which will be discussed in greater detail during the Applicant Consultation with the PCORI Review Panel, are provided
in the **Standard Questions for Applicant Consultation Template**. Applicants **must provide PCORI with the requested information by June 1, 2021, if selected to participate in an Applicant Consultation.**

Note: There may be additional programmatic questions not included in the Standard Questions for Applicant Consultation Template that are unique to an application. Responses to application-specific questions will not be due by the June 1 deadline, but they must be addressed during the Applicant Consultation meeting. All templates are posted on the landing page for this targeted funding announcement so that the applicants can review and begin to prepare required materials ahead of the Applicant Consultation, if invited to participate.

The PCORI Review Panel will provide an online evaluation and score based on PCORI’s merit review criteria prior to the Applicant Consultation for each invited application. During the Applicant Consultations, the PCORI Review Panel will discuss applications directly with the PI and AO to further assess the merits of the proposed research and to address the institution’s readiness to execute and complete an award in the timeline expected for this funding opportunity. A PCORI Contract Management staff member, who will not be a Review Panel member, will participate in the Applicant Consultation to address contractual expectations and procedures with the applicant study team.

Each application that progresses to the Applicant Consultation stage will receive a merit review score and discussion summaries consistent with standard PCORI merit review processes.

**PCORI Merit Review Criteria**

Below are PCORI’s merit review criteria for this funding announcement. In accordance with standard PCORI merit review processes, merit reviewers will use these criteria during the preliminary online and panel discussion review phases to evaluate and score applications and to ensure consistency and fairness in how applications are evaluated.

**Criterion 1. Potential to address an important and compelling clinical or care delivery question raised by COVID-19.**

The following questions should be addressed:

- Would the study findings significantly contribute to understanding strategies that would mitigate the impact of COVID-19 on patients, communities, clinicians, and other healthcare workers, or healthcare systems?
- Does the application demonstrate that the research question is important to relevant stakeholders?
- Would the study findings be a novel or compelling contribution to the field of COVID-19 research?

**Criterion 2. Potential for the study to generate actionable findings to inform clinical practice and/or public health responses, decision making, and planning**
The following questions should be addressed:

- Does the application describe how the study would result in actionable findings and identify potential end users of these findings?
- Are potential barriers to uptake of the study findings identified and addressed?

Criterion 3. Scientific merit (research design, analysis, and outcomes). The research design should show sufficient technical merit to ensure that the study goals will be met.

The following questions should be addressed:

- Does the application describe a clear causal framework that informs the research design, key variables, and relationships being examined?
- Are the study design, study setting, and selected comparators adequately described and justified?
- Does the proposed project demonstrate a rigorous methodological approach, and will the research strategy address the research question? (For example: Are sample sizes and power estimates appropriate? Are outcome measures appropriate and validated? Is the analytic plan well described and justified?)
- Is the project feasible in the proposed timeline?

Criterion 4. Investigator(s) and environment

The following questions should be addressed:

- Do members of the research team have track records demonstrating that they are qualified and capable of successfully completing the proposed project?
- Are the relevant necessary areas of expertise represented on the research team?
- Are the levels of effort for team members appropriate for the proposed work?
- Is the research environment appropriate to support the proposed project, and will the team have access to the resources necessary for success?

Criterion 5. Patient-centeredness

(Note: A study can be patient centered even if the end user is not the patient—as long as patients will benefit from the study findings.)

The following question should be addressed:

- Does the application describe which outcomes (potential benefits and harms) are important to patients and relevant stakeholders?
- Is the burden to research participants reasonable, given the research question?

Criterion 6. Patient and stakeholder engagement

The following questions should be addressed:

- Does the application describe involvement with the stakeholder groups that are most relevant and appropriate?
• Does the application describe a process for engagement and the decision points at which engagement activities will occur?
• Does the application describe dissemination to those who could use the study findings to inform healthcare decisions? Does the project engage the stakeholder organizations ultimately needed for effective dissemination?

Post–Applicant Consultation
After the Applicant Consultation, PCORI program staff review final scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff then recommend projects to a Selection Committee, which is a committee of the Board of Governors. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI’s strategic priorities. For this PFA, the Board of Governors has delegated the funding approval authority to the Executive Director.

Summary Statements and Funding Recommendations
Applications that do not advance to the Applicant Consultation phase will be notified that their application is no longer being considered for funding and may be encouraged to apply to other funding opportunities. Applications that do advance to the Applicant Consultation will receive a written summary statement consistent with PCORI merit review practices.

Funding recommendations are made by identifying meritorious applications that fit programmatic needs and that satisfactorily address the merit review criteria. PCORI also considers the funds allotted for the current PFA when deciding which applications to recommend to the Executive Director for approval. Applicants to this expedited PFA that are invited to present their application in an Applicant Consultation will receive notification of the funding status of their application and review summary statements in July 2021.

PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting
Applicants should be aware that all PCORI awardees are required to comply with the following requirements:

Registering Research Projects
PIs are required to use the naming convention “PCORI-PCORI application number” (i.e., PCORI-XXXX-XXXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the
definition on the NIH database\textsuperscript{15} (see Data Element Definitions) are required to register, if funded. Funded clinical trials or observational outcomes studies must be registered at ClinicalTrials.gov. Funded evidence-synthesis studies must be registered at PROSPERO.\textsuperscript{16} Funded patient registries must be registered at https://patientregistry.ahrq.gov/.

PCORI Public Access Policy
PCORI requires all awardees to adhere strictly to PCORI’s publication policies, which will be shared with awardees within the research contract.

Standards for Privacy of Individually Identifiable Health Information
On August 14, 2002, the Department of Health and Human Services issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the Department of HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights\textsuperscript{17} provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available from NIH.\textsuperscript{18}

Data Management and Data-Sharing Plan
PCORI is committed to publishing and disseminating all information and materials developed using PCORI funding, in accordance with its authorizing legislation. All recipients of PCORI contracts must agree to these principles and take steps to facilitate data availability.

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. As such, if an award is made, the awardee will be expected to adhere to PCORI’s Policy for Data Management and Data Sharing. A full data management and data sharing plan is not required at the time of application. If an award is made, the Awardee is required to develop and maintain such a plan which is described in detail in the PCORI Methodology Standards for Data Integrity and Rigorous Analyses, specifically Standard IR-7.

The information here is meant for informational purposes only and does not attempt to be an exhaustive representation of the Policy for Data Management and Data Sharing. Please refer to the

\textsuperscript{15} Available at https://prsinfo.clinicaltrials.gov/
\textsuperscript{16} Available at http://www.crd.york.ac.uk/prospero/
\textsuperscript{17} Available at http://www.hhs.gov/ocr/
\textsuperscript{18} Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html
Policy in its entirety for additional information.

Peer Review and Release of Research Findings
PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. Accordingly, the PCORI Board of Governors (Board) adopted the Process for Peer Review of Primary Research and Public Release of Research Findings.19

In summary, Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and interprets the findings in clinical or other decisional contexts. After Awardee Institutions have responded to reviewers’ comments to PCORI’s satisfaction, the report will be accepted and considered final. PCORI will then prepare two 500-word standardized abstracts summarizing the study results (as detailed below), which the Awardee Institution will review and approve.

No later than 90 days after the draft final research report is accepted, PCORI will post the following materials on its website: (1) a 500-word abstract for medical professionals; (2) a 500-word standardized abstract summarizing the study results for patients and the general public; (3) a link to the study record on ClinicalTrials.gov (as applicable); and (4) ancillary information, including conflict of interest disclosures. The final research report, along with anonymized reviewer comments, will be made publicly available on the PCORI website no later than 12 months after its acceptance, except by prior mutual agreement with the Awardee Institution.