PCORI Cycle 2 2021 Expedited Targeted PFA

*Increasing COVID-19 Vaccine Confidence among Long-Term Care Workers*

Submission Instructions

Published April 13, 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 our 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 that comes from research guided by patients and other stakeholders.

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I. About These Instructions

This document provides key information to help researchers prepare for and respond to the Patient-Centered Outcomes Research Institute (PCORI) Expedited Targeted Funding Announcement (PFA): Improving COVID-19 Vaccine Confidence Among Long-Term Care Workers.

These instructions should answer many questions applicants may have, but the following resources are also available:

See PCORI’s Applicant FAQs¹ for common questions about PCORI and the standard application process; not all FAQs may apply for this expedited PFA.

Visit PCORI’s Help Center² for additional applicant resources.

- For Programmatic Inquiries: Contact the PCORI Helpdesk via email at sciencequestions@pcori.org, phone at 202-627-1884, or online at http://www.pcori.org/PFA/inquiry.
- For Administrative, Financial, or Technical Inquiries: Contact the PCORI Helpdesk via email at pfa@pcori.org, or phone at 202-627-1885.
- PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to an application deadline.

It is the applicant’s responsibility to submit the application on or before the deadline. Refer to PCORI’s Policy on Funding Application Submission.³

Administrative Considerations

To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFA, FAQs, and Submission Instructions. Applicants that fail to submit the required documents may be rejected from the merit review process. All rejection decisions are final.

Unless otherwise stated in the Submission Instructions, all materials submitted on behalf of an applicant organization are the property of that organization. PCORI will not share or publicize the contents of an organization’s application.

Funding Mechanism

PCORI utilizes a contract mechanism, not a grant mechanism, for its awards. PCORI funds projects that demonstrate the highest probability of being completed on time and within budget, and meeting all milestones and deliverables. Applicants must submit representative budget information and Research Plans that allow the project to conclude within the approved contract term.

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period. Applicant institutions and the Administrative Officials are advised to carefully review PCORI’s standard contract templates provided on the Awardee Resources page on the PCORI website.⁴ Note that international awardees will be issued a contract in U.S. dollars. Fluctuations in currency exchange rates will have no bearing on the contract value, nor will adjustments

¹ Available at http://www.pcori.org/content/faqs-applicants/.
² Available at http://help.pcori.org/hc/en-us/.
³ Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.
be made to accommodate losses or gains associated with such currency fluctuations.

**Award Funding Conditions**

At any time during the contract, PCORI reserves the right to discontinue funding for awardees that fail to meet the mutually agreed upon milestone, which are finalized in contract negotiations and prior to execution. See PCORI’s [Standard Contract Template](#) for more information.

**II. Who Can Apply**

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college hospital or healthcare system; any laboratory or manufacturer; or any unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Organizations may submit multiple funding applications. Individuals are not permitted to apply. If you have questions about eligibility, contact [pfa@pcori.org](mailto:pfa@pcori.org).

Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be shown clearly. However, PCORI’s general preference is that prime awards be made to a U.S.-based organization.

A prime award contract to a non-U.S.-based organization should be carefully justified and preferably include a key U.S.-based organization and co-Principal Investigator as a subcontractor. In assessing whether a research award can be made to a non-U.S. organization as a prime contractor or subcontractor, and/or whether the research can be conducted outside the United States, PCORI will carefully review and consider the following factors:

- The research funded by PCORI must result in findings that are relevant and useful to U.S. patients and healthcare decision makers.
- The proposed project must demonstrate that essential scientific needs will be met by conducting the study outside the United States or having the study conducted by non-U.S. research organizations.
- The proposed study must demonstrate meaningful effort and involvement of U.S. organizations and investigators with pertinent expertise and experience to contribute to the project. The engagement plan for the proposed study should also adequately and sufficiently include U.S. patients and stakeholders and have clear relevance to the U.S. healthcare system.

**III. How To Apply**

Applying for this expedited PFA is a two-stage process: (1) Application Submission (in PCORI Online) and (2) Applicant Consultation (virtual meeting with PCORI Review Panel). To submit an application, including all required documents, follow the instructions provided in this document and in [PCORI Online](https://pcori.force.com/engagement). All documents must be submitted through PCORI Online.
To apply for PCORI funding, an applicant (PI or PI designee) must register in PCORI Online. To submit an application or to register your organization in PCORI Online, you need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). You can apply for a DUNS number⁶ and an EIN,⁷ if applicable. To register, you must provide a name, an email address, a password, and a security question and answer. Once signed in, you will be directed to the home screen. Click on the Research Awards tile to apply for funding. PCORI strongly recommends that only the PI create the application record, because whoever creates the record will have permanent access to it in PCORI Online.

Step 2: Submit an Application

To submit an application, log in to PCORI Online, complete the required fields, and upload the completed PFA-specific Templates into the system.

PIs can download the Templates from the PFA page in the PCORI Funding Opportunities web page. For formatting instructions, reference Step 3.

For detailed instructions on how to navigate the system, reference the PCORI Online: Pre-Award User Guide for Research Awards.⁸

Step 3: Format and Complete Required Templates

Required templates are on the PCORI Funding Opportunities⁹ web page. Find the PFA to which you are applying and download the correct PFA-specific templates, because they vary among PFAs and cycles. Keep the following in mind:

- Do not reorganize sections within the templates.
- Do not alter the templates’ main header questions within your submission.
- You may delete instructional text.
- Adherence to font size, type density, line spacing, and text color requirements is necessary to ensure readability and fairness.

You must format all required documents as follows:

- **Header**: Include the PI’s full name in the top-left corner of every page.
- **Font**: Use Calibri size 11 font for body text and size 8 font for figures, tables, and captions.
- **Type Density**: Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line Spacing**: Use single spacing. Must be no more than six lines per vertical inch.
- **Text Color**: No restriction. Though not required, black or other high-contrast colors are

⁹ Available at [http://www.pcori.org/funding-opportunities](http://www.pcori.org/funding-opportunities).
Legibility is of paramount importance. Applications that include attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

**Step 4: Upload Required Documents**

Follow the [Submission Checklist](#) to enter required information. Upload required documents to PCORI Online in the correct order and required file name format. When instructed, use Adobe Acrobat Professional to combine documents into a single PDF file for upload.

Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your submission for review, analysis, and reporting, as well as the legibility of the file.

Applicants must follow the detailed file name format and file upload type described in the [Submission Checklist](#).

Within the Templates & Uploads tab, click “Choose file” to select a file from your computer, and click “Upload.” For detailed instructions, refer to the Templates & Uploads section of the [PCORI Online: Pre-Award User Guide for Research Award](#).

**Step 5: Submit for Authorization**

Once you have completed and uploaded all required information, select “Review & Submit,” and then select “Submit” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the 5 pm (ET) deadline. PCORI Online will email the AO, but the PI should notify the AO when the application is ready for review, AO approval, and submission. The PI and the AO may not be the same individual. Both the AO and the PI will receive an email confirming that PCORI has received the application.

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10 See [adobe.com](http://adobe.com) for more information on Adobe Acrobat Professional.
IV. When To Apply

Deadlines for each funding cycle are noted in the PCORI Funding Opportunities web page and in the PFA. System or technical issues with PCORI Online that affect the on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, in the PCORI Submission Instructions, or in PFAs are not valid issues warranting consideration of a deadline extension. See PCORI’s Policy on Submission of Research Contract Applications\(^\text{11}\) for complete information.

V. Application Submission: What to Include

Applicants are encouraged to review this entire section. Print and complete the Submission Checklist to ensure that the application is submitted correctly. Download all required templates from the PCORI Funding Opportunities\(^\text{12}\) web page and enter or upload required information in PCORI Online.

Apply in PCORI Online

Download and complete the appropriate templates from the PCORI Funding Opportunities web page. Instructions appear in gray italics. Replace the gray italics and any instructional text with your responses, but retain all bold headings and question numbers. Note that additional template modifications will result in the disqualification of your application.

The content included in these templates will be used as the primary source of information for PCORI’s Programmatic Screening process. Focus on including only critical information, as space is limited. Provide a description that allows the PCORI Review Panel to understand the project, including the aims and study design. Review the PFA for Maximum Project Budget (direct costs) and duration information. The page limit does not include references. PCORI suggests including all references as in-text citations using AMA style, but other citation styles are accepted. Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the templates for application submission.

Following application submission, all applications will be evaluated through PCORI’s Programmatic Screening process. Not all applications will be invited to an Applicant Consultation. See the PFA for more information about Programmatic Screening following application submission.

PI and Contact Information

Enter the following information directly into PCORI Online. PCORI refers to three specific roles with particular responsibilities. Keep the following in mind as you complete this section:

Principal Investigator (PI)

A. Description

- The PI is responsible for the project’s engagement, scientific and technical aspects, and peer review–related activities.
- The Contact PI’s institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in the same

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\(^{11}\) Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.

\(^{12}\) Available at http://www.pcori.org/funding-opportunities/.
or a different role, such as co-investigator or consultant. Refer to the [Who Can Apply](#) section for specific instructions.

- If electing to submit an application with two PIs, you must designate one as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI’s primary point of contact for all communication. **No more than two PIs can be named on an application.**

**B. Activities**

- The PI (or PIs) assumes responsibility and accountability for research execution, compliance, and organizational conduct.
- If applicable, the Contact PI is responsible for submitting the application, submitting all progress reports, and serving as PCORI’s programmatic and administrative contact. PCORI will send all communication to the Contact PI, and it is his or her responsibility to share PCORI communications with PI #2.
- The PI (or PIs) manages day-to-day project operations.
- The PI (or PIs) acts as the organization’s lead research representative.

**Administrative Official (AO)**

**A. Description**

- The AO is responsible for matters related to the award and administration of the contract.
- The AO cannot be the PI.
- The AO’s signature certifies that the organization will be accountable for appropriately using the funds awarded and for performing the PCORI-supported project.

**B. Activities**

- The AO manages contract activation, modifications, and additional required administrative matters.
- The AO certifies contract compliance of all applicable assurances and certifications referenced in the application.

**Financial Official (FO)**

**A. Description**

- The FO is responsible for all required financial reporting.

**B. Activities**

- The FO completes and certifies expenditure reports on behalf of the organization.
- The FO accounts for contract funds and submits invoices and payment details.

**Key Personnel**

Enter the following information directly into PCORI Online. PCORI identifies key personnel as any individual who is critical to the project’s scientific development and execution in a measurable way and whose absence from the project would affect the likelihood of success.
Note the following:

- Applications can include up to two PIs.
- PIs can serve in other roles (e.g., dual-PI, co-PI, co-investigator, or consultant) on other applications.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See PCORI's Glossary for “Consultant” and “Subcontractor” definitions.
- Applicants should identify patient and other stakeholder partners, whether individuals or organizations, if known. If all partners have not been confirmed by the time of application, then applicants, if funded, must submit updated partner information to PCORI as part of the Updated Engagement Plan milestone. (Note: Patient and stakeholder partners will be publicly listed on the PCORI website and may be included on public communications. In providing the names of partners, applicants acknowledge that partners have consented to the disclosure of their names to PCORI and to making their names publicly available. If a patient or other stakeholder partner chooses to remain anonymous, contact pfa@pcori.org for guidance.)
- PCORI will request a completed Key Personnel Template with biosketch information if applicants are invited to participate in the Applicant Consultation.
- PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.
- If awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post–contract execution.

**Project Information**

Enter the following information directly into PCORI Online.

**Technical Abstract**

Provide a Technical Abstract within PCORI Online that summarizes your Research Strategy. The abstract must include the following sections:

- **Background and Significance**: State the problem or question the research is designed to address.
- **Study Aims**: Briefly describe the specific aims of the study, including specific research questions and long-term objectives.
- **Study Description**: Describe in detail the study design. Include, as applicable, the following:
  - **Overall study design**
    - Identify the study design that most closely matches your project. This list is not exclusive. If your study does not fall into one of these categories, please insert the most appropriate description.
    - Randomized controlled trial
    - Cluster randomized trial
    - Stepped wedge design
    - Quasi-experimental study
    - Observational: cohort study
    - Observational: case-control study
    - Observational: cross-sectional study
  - **Main components of the intervention and comparator(s)**
    - Name or briefly describe each intervention/exposure and comparator. Do not use brand names. If “usual care,” define what this will be.
Study population
- **Describe population studied; including**
  - Source
  - Number of participants/target sample size by arm
  - Inclusion criteria (if including age, describe as “adults ages 45-85” or “children age 5 or younger”)
  - Demographic information
  - Clinical status

Primary and secondary outcomes
- **Include all primary and secondary outcomes. If study has both primary and secondary outcomes, use this approach:**
  - Primary: List primary outcomes in series, separated by commas
  - Secondary: List secondary outcomes in series, separated by commas

Timeframe
- **Specify the most distant follow-up point for the primary outcomes. (Do not need to specify length of exposure to intervention.) For example:**
  - 18-month follow-up for primary outcomes
  - Up to 7-year follow-up from the time of diagnosis (an example of a retrospective cohort study)
  - Immediate follow-up for primary outcomes

For examples of completed Study Design tables, see:
- Comparing the Benefits and Harms of Medicines for Long-Term Treatment of Blood Clots -- The ALTERNATIVE Study
- Comparing Treatment Options for Children with Urea Cycle Disorders

Public Abstract

Provide a description of your project, written in lay language that the general public will understand. Describe:
- The health condition or problem being studied. Include enough information to provide context for a reader who is unfamiliar with the topic, such as the scope, severity or burden posed by the problem
- The rationale for and importance of the study
- The study’s objective(s) and specific aims
- A brief non-technical description of the study design
- Who can use results from this study and how (i.e., what is the decision that results from this study will help end-users make? What will they be deciding between, and in what situation?)
- The patient population and how they will be recruited for the study
- The study intervention(s), making sure to define all study arms/comparators, including what any control or usual care group received, and any acronyms or technical terms used
- All primary and secondary outcomes, the intervals at which they will be measured, and how (e.g., electronic health record data, survey, clinical assessment, etc.)
- Stakeholder engagement: what types of stakeholders are represented, and in what ways are they involved in the study

If your project is approved for funding, the PCORI Translation Center will edit your summary to ensure it
is consistent with PCORI style. The final version will be sent to you for sign-off.

For examples of completed public abstracts, see:

- Comparing Two Ways to Provide Palliative Care to Older Adults with Serious Illness
- Comparing Programs to Treat Opioid Use Disorder in Primary Care and Substance Use Clinics

Application Submission File Uploads

Upload the required templates into PCORI Online: (1) Research Plan Template, (2) Budget Materials Template, and (3) PI Template (biosketches for PI/Dual PI).

Research Plan Template (Upload 1 of 3)

Complete all required sections in the Research Plan Template and upload as a single PDF to PCORI Online. The Research Plan includes the Research Strategy, Research Team and Environment, Dissemination and Implementation Potential, Return of Aggregate Study Results, Protection of Human Subjects, References Cited, and an optional Appendix.

Research Strategy

In this component of the Research Plan (up to 6 pages), applicants must describe their Research Strategy and work plan, and demonstrate how the proposed study responds to this PFA. The Research Strategy includes the following sections: (A) Specific Aims, (B) Significance, and (C) Study Design or Approach.

In addition to following the instructions in the Research Plan Template, applicants should ensure that the Research Plan addresses the following points:

**Addressing a decisional dilemma meaningful to stakeholders.** Applicants should state the specific clinical decision(s) or treatment choice(s) confronted by decision makers and explain how the findings from the proposed research will inform those decisions. State why this decision—such as choosing a specific care delivery strategy to treat a condition or manage a specific population—is important. Document the uncertainty that stakeholders face in making this decision.

**Selection of outcomes that are important to patients and other decision-makers.** Applicants should document how the primary and/or secondary outcomes are relevant and meaningful endpoints to patients and other stakeholders.

**Detection of meaningful effects.** PCORI specifically seeks studies that are powered to detect meaningful effects. Applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. For example, the application must state all the necessary assumptions, such as the outcome(s) on which the power calculations are based, the estimated difference in the effect size between study arms, the standard deviation of the effect size measure, the type I and II error rates, and any other assumptions. All such estimates must be justified by referring to prior published research or preliminary data.

**Ensuring valid estimates of intervention effects.** Applicants must specifically discuss their capacity to measure such factors as differential adherence to chosen treatments (or participation in intervention programs) that could result in differences in the effectiveness of the alternative interventions being compared in clinical populations.

**Leveraging existing resources.** Applicants proposing use of an existing research network infrastructure, research consortia, or related data resources (e.g., electronic medical records data from healthcare
delivery systems or administrative claims data from public or commercial insurers) should address this with sufficient specificity in the Research Plan, as appropriate. Applicants should also refer to the PCORI Methodology Standards for Data Networks as Research-Facilitating Structures.

**Engagement with patients and other stakeholders.** Applicants should describe how they will work with patients and other stakeholders on their study and the added value their experience and expertise will bring. In this section, briefly identify the types of stakeholders that will be engaged as research partners, the rationale for selection, including how they represent the diversity of the people affected by the problems this study addresses, and the scope of their involvement. Include the names of patient and other stakeholder partners and their organizations if known at the time of application. If unknown, applicants should describe a plan for identifying and selecting research partners. [PCORI’s Engagement Rubric](https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-120919.pdf), and other engagement resources available on PCORI’s website can be a helpful resource to guide applicants on engagement approaches to consider in different phases of a research study. Funded studies will be required to submit a full roster and detailed Engagement Plan at two months after contract execution.  

**Research Team and Environment**

Within the Research Team and Environment component (up to two pages) of the Research Plan Template, applicants must 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. Applicants must also describe the following:

- How and why those research sites were selected
- How they tie back to the research project
- The resources, facilities, support, and collaborations available to ensure the project’s success
- If multiple sites are involved, prior experience that demonstrates the likelihood of working together successfully (e.g., past data sharing, Institutional Review Board (IRB) reciprocity, or other factors) to facilitate efficient conduct of the study
- Ways in which the project will benefit from the research environment’s unique features or from community involvement
- How sites will work together to ensure that milestones will be achieved
- Institutional and community investment in the success of the research, such as the availability of organized peer groups
- Logistical support, such as administrative management and oversight, and best practices training
- Financial support, such as protected time for research with salary support
- Access to and support of patient groups

If invited to participate in the Applicant Consultation, additional details on all key personnel, including professional and partner profiles/biosketches, should be provided within the [Key Personnel Template](https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-120919.pdf).
**Dissemination and Implementation Potential**

In this component (up to one page), applicants should describe specific opportunities as well as possible barriers to disseminating and implementing their work in other settings. This section should address any study limitations that could have an impact on the usability of findings (e.g., propriety issues, applicability, scalability, and appropriate settings of care).

PCORI does not support awardees budgeting efforts or resources for the conduct of dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications for funding to support dissemination and implementation efforts through separate PFAs and other mechanisms.

*Note:* PCORI encourages researchers to submit documentation of any implementation agreement with the sponsoring organization, confirming that the organization will implement successful interventions on a large scale. PCORI will view this agreement as a positive factor during merit review. Include this with the Research Plan PDF document as the last item.

**Return of Aggregate Study Results**

In this component (up to half a page), applicants should describe how, as awardees, they plan to communicate the aggregate findings from their research to the participants who were enrolled in the study. Note that the proposed activity should return **aggregate** study results (i.e., the overall study findings) to the study participants, and not **individual** results (i.e., participant-specific data, such as genetic or imaging results). Results return may be accomplished by sharing the lay language “Results Summary” that PCORI posts to its website upon completion of the research project, or by distributing a similar summary. Applicants may propose to distribute the study results to study participants by email, mail, newsletter, or other approaches.

Specify the costs associated with this return of results to study participants. Studies with fewer than 5,000 participants may budget up to $2,500. If this amount does not suffice for studies that need to return results to a larger number of participants, applicants may propose a larger amount with justification. Note that the costs associated with the return of results must be included as part of the budget materials when determining compliance with the Maximum Project Budget in the PFA.

Applicants should consider whether they will need to obtain IRB approval ahead of the study in order to recontact participants at its conclusion. In addition, awardees should make all efforts to ensure that returning results is in accordance with their institution and/or state’s guidelines and laws.

Studies may be exempt from this provision if a return of results is not possible. For example, this provision does not apply to studies that use secondary data or those that use anonymous participants. If applicable, applicants’ response to this section should address why the return of results is not feasible.

**Protection of Human Subjects**

In this component (up to three pages), describe the protection of human subjects involved in your research. PCORI follows the Federal Regulation for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, see Section 5, “Human Subjects Research Policy,” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which was issued by the U.S. Department of Health and Human Services.

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Required Education of Key Personnel on the Protection of Human Subject Participants requirement as you complete this section.

References Cited

This component (up to five pages) is included in the Research Plan Template. Throughout the Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation for each reference. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title and journal or book title, the volume number, the page numbers, and the year of publication. Include only bibliographic citations. PCORI suggests following AMA style when providing citations for source materials used to prepare any section of the application, but other citation styles are acceptable. Citations that are publicly available in a free online format may include URLs or PubMed ID numbers along with the full reference. Limit references to relevant and current literature. Be concise and select only those literature references pertinent to the proposed research, so that you do not exceed the page limit. Reference websites in the standard URL format (i.e., http://www.pcori.org) along with the date on which the link was last accessed.

Appendix (Optional)

This component (up to five pages) is included in the Research Plan Template. Applicants may provide additional materials to support the proposed study (e.g., survey instruments and interview guides). Note that the PCORI Review Panel is not required to review this section.

The Research Plan template should be uploaded to the Templates & Uploads tab of the application dashboard with the following naming convention “ResearchPlan_PI LastName.pdf”

Budget Materials Template (Upload 2 of 3)

Complete all required sections in the Budget Materials Template, including Section 1: Budget Summary and Section 2: Budget Justification. Upload as a PDF in the designated fields in PCORI Online. See Appendix 2: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI funding.

Applicants must justify the costs for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget. Costs should be included for each budget category in the Budget Materials Template.

Explain the basis for costs, the reason why the costs are necessary to the project, and the reason for major cost variances. Include information about budgeting for engagement, including financial compensation of patient and stakeholder partners, costs of patient and other stakeholder expenses, project staff salaries, engagement event and/or meeting costs, and expenses for incorporating partner feedback.

Note that some projects employ or assign an individual to coordinate or manage all project-related patient and stakeholder engagement. This person should be listed as full-time equivalent under personnel, consultant, or subcontractor costs.

Explain the basis for travel costs and describe how the travel is related to the proposed research and necessary for achieving programmatic objectives. Applicants must also include each participant’s annual salary, level of effort, and requested salary. The purpose of this information is to help ensure that salaries do not exceed the PCORI salary cap: $200,000 annualized per individual, per year, exclusive of...
fringe benefits.

PCORI will evaluate each member’s contribution to validate meaningful contributions and assess whether overlap in responsibilities occurs. Provide a clear distinction between individuals who should be key personnel and those who should be classified as “other” personnel.

Specify any additional sources of funding, currently available or anticipated, to support the proposed research project. Include funding amounts and the period when the funding will be available. Use continuation pages as needed.

Applicants proposing use of an existing research network infrastructure, research consortia, or related data resources must provide documentation supporting the involvement of network leadership throughout the study (e.g., budget materials that cover the costs of the network’s efforts).

Note: PCORI will not fund a project that is already funded through another funding entity. By submitting an application to PCORI, the AO is certifying that no overlap in funding exists at the time of submission. Before receiving a PCORI contract, awardees must disclose all current and pending support.

The Budget Materials Template should be uploaded to the Templates & Uploads tab of the application dashboard with the following naming convention: “Budget_Materials_PI LastName.pdf”

Note: A fully itemized, detailed budget is not required for application submission to this expedited PFA. However, if an application is selected for an Applicant Consultation, then additional information must be provided to PCORI for that meeting, including Detailed Budgets for the prime institution and all subcontractors. Applicants are encouraged to populate the Detailed Budget Template so that it is ready when requested by PCORI for the Applicant Consultation.

**PI Template (Upload 3 of 3)**

Applicants must complete the PI Template for the lead researcher(s). Alternatively, the most recently posted NIH-formatted biosketch may be used. Depending on the nature of the proposed study, a collaborative and multidisciplinary team might be required. PCORI permits applicants to name a maximum of two PIs within an application. The PIs may be from the same or different institutions. Each PI is accountable and responsible for the conduct of the award and for ensuring that all milestones, deliverables, and reports are completed in accordance with the award terms and conditions. Patient and stakeholder partners serving as a PI may choose to complete, in lieu of the PI Template, the Patient and Stakeholder Partner Profile/Biosketch form. Do not exceed five pages per person. You may delete the instructional text.

If proposing a dual-PI application, applicants must designate one individual as the Contact PI. The Contact PI must be employed by the applicant institution and listed first within the application. Although PCORI will recognize both PIs, the Contact PI is responsible for submitting the application and for communications between the PIs and PCORI, including coordinating meetings with PCORI staff.

PCORI is especially interested to learn how previous experience, past performance, and training in the field of PCOR has prepared each team member to conduct this research. Applications must also describe the background, relevant experience, and roles of patient and stakeholder partners.

Applicants must assemble a research team that is suited to complete the work. Applications must demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will aid in achieving the project goals. **Note: If an Applicant Study Team is invited to participate in an Applicant Consultation, then PCORI will request additional**
information in the Key Personnel Template; however, applicants should not provide this information during initial application submission.

The PI Template PDF should be uploaded to the Templates & Uploads tab of the application dashboard with the following naming convention: “PI_Template_PI LastName.pdf”

VI. Applicant Consultation: What to Include

Following application submission, PCORI will conduct the Programmatic Screening process and identify a subset of applications to proceed to a virtual Applicant Consultation with the PCORI Review Panel (see PFA for additional information). Applicants must be available to participate in this activity between June 7 and 16, 2021.

If an Applicant Study Team is invited to participate in this stage of the review, the following additional materials will be required for submission to PCORI by June 1, 2021, ahead of the Applicant Consultation: Standard Questions Template, Milestones Template, Key Personnel Template, Detailed Budget Template (for Prime and Subcontractors), and Letters of Support.

Standard Questions for Applicant Consultation Template

If the applicant is invited to an Applicant Consultation, a set of standard questions will be emailed to the PI and AO in advance of the meeting. Please submit responses to the questions in a Word document (not to exceed five pages) as supplemental information to your application by June 1. Refer to the Standard Questions for Applicant Consultation Template and the PFA for additional information. Note: There may be additional programmatic questions beyond the Standard Questions for Applicant Consultation Template that are unique to an application. Responses to any such questions will not be due by the June 1 deadline but must be addressed during the Applicant Consultation meeting.

Milestones Template

Milestones are concrete, specific events or accomplishments that are documented by deliverables and associated with a timeline and that must include project objectives to be accomplished at specific dates during the proposed project. Each reporting period should include the major milestones reflecting the research activities and only those activities that the PCORI contract supports. For this PFA, prespecified milestones have been identified in the Milestones Template and must be met for a project to be eligible for funding.

Applicants must complete the Milestones Template and upload it as an Excel file, not as a PDF, in PCORI Online. Follow the instructions in the Milestones Template and complete all required sections. For the milestones provided in the template, based on Milestone—Deliverable Name (column B) and Description (column C), applicants must provide the Due Date (column D). Consider the guidance information in column E as you determine the due date, which can be any day of the week but must fall within the timeframe stated in the Milestones Template. Applicants should insert rows for additional milestones, when and where appropriate as they would correspond to the timing of the milestone.

Interim and final deliverables must adhere to the associated templates and will be included in your research contract if your application is funded. Note that PCORI reserves the right to request additional deliverables during the life of the project.
Key Personnel Template

The Key Personnel Template must include all biosketches/profiles for the remaining study team members identified as key personnel. Complete a Profile/Biosketch section (up to five pages per individual) for each person listed as key personnel, copying the tables provided as needed. At a minimum, each profile must include the person’s name, title, and degree(s). PCORI is especially interested to learn how previous experience, past performance, and training in the field of PCOR has prepared each team member to conduct this research. You must also describe the background, relevant experience, and roles of patient and stakeholder partners.

Detailed Budget Template

Complete the Detailed Budget Template for the prime institution and subcontractor and submit it to PCORI. For each program year, complete a Detailed Budget for the prime institution and each subcontractor proposed in your application. All personnel information must be entered in the Project Personnel tab corresponding to that year in this template. Add additional rows for personnel as needed. Refer to Appendix 1: Detailed Budget Overview and Appendix 2: Allowable and Unallowable Costs.

Detailed Peer-Review Budget for Peer Review-Related Costs

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 adopted the Process for Peer Review of Primary Research and Public Release of Research Findings. The detailed Peer-Review Budget must include costs related to the development and revision of the Draft Final Research Report (DFRR), as part of PCORI’s Peer-Review Process. The Peer-Review Budget should be completed in the Detailed Budget Template. Note that PCORI looks at the Total Budget, which includes the Peer-Review Budget and the Research Project Budget, when determining compliance with the Maximum Project Budget in the PFA.

- The DFRR should be submitted 3 months after completion of the milestone for Completion of Data Analysis for All Study Aims and expected to have finished the Peer-Review Process and be accepted by PCORI within 6 to 12 months of submission (following necessary revisions).
- Costs associated with the Peer-Review Process are limited to those personnel, consultants, and subcontractors who will be assisting the PI in the development of the DFRR and responding to any requested revisions as part of the external review.
- The Peer-Review Budget must be included in the Budget Materials Template. The PI must dedicate measurable effort in support of the Peer-Review Process. Applicants must identify the peer-review support staff role within the budget at the time of submission.

Letters of Support

Save all Letters of Support as a single PDF file using the Letters of Support Table as the first page of the file. Follow the guidance below and in the table template to enable easy reference for the PCORI Review Panel. Reviewers are asked to consider the Letters of Support as outlined in the template and in this guidance.

All Letters of Support must be addressed to the PI and demonstrate the commitment of key personnel

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and supporting organizations (e.g., dual-PI, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of Support are not required for personnel who are not contributing in a substantive, measurable way to the project’s scientific development or execution. Letters of Support must reflect clearly the involvement and material contribution to be provided by the signatory parties and are meant to confirm the commitment of collaboration.

PCORI may contact any individuals or organizations included in the Letters of Support with questions or to confirm support as described in the letters.

Letters of Support must be organized as follows:

- **Letters of Organizational Support**: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, that confirms the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. PCORI also strongly encourages you to provide a letter from the department or organization leadership affirming support to disseminate research findings that are appropriate and warranted for implementation.

- **Letters of Collaboration**: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of Support from patient and stakeholder partners must describe clearly the origin of the study topic and the role of the partners in defining the question, comparators, goals and outcomes, and so on. PCORI also strongly encourages letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation. Include a Letter of Support for each consultant verifying the work to be performed and the negotiated rate.

- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources**: If the proposed Research Plan involves access to patient populations, data sets, or additional resources, include a Letter of Support that confirm such access, signed by the person with approval authority. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

List all letters in the table (adding rows as needed), and include the page number on which each letter can be found in the single PDF file.

**If Selected for Funding**

If selected for funding, PCORI will require additional information from awardees prior to contract execution.

**Methodology Standards Checklist**

If selected for funding, awardees must complete the [PCORI Methodology Standards Checklist](#) as an early deliverable. Refer to the [PCORI Methodology Report](#) for explanations of the standards.
VII. Appendix 1: Detailed Budget Overview

Note the following:

A. Personnel Costs

- Personnel costs include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are key personnel and those considered “other” personnel.
- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.
- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. Provide documentation to support the fringe benefits within the Budget Justification.
- Level of Effort: Personnel who contribute to a PCORI-funded research project must monitor their total percentage of effort across all of their active funding, so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort if funded. You must report effort by the percentage of time over the course of the project year. If you are not requesting salary support, use $0 for the base salary.
- All personnel who dedicate effort to the project must be listed on the Personnel Budget with their level of effort, even if they are not requesting salary support. List the base salary for each person in the Budget Justification and the Detailed Budget. Describe the individual’s specific functions in the Budget Justification. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Salary Cap: The PCORI base salary cap for personnel is $200,000 annualized per individual, per year, excluding fringe benefits. An individual who earns less than $200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than $200,000 must use $200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- Inflation/Cost of Living Adjustments may only be assessed on base salaries less than the $200,000 salary cap.
- Fringe Benefits: These costs are calculated based on the institution’s own policy. In the Budget Justification upload, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

  Note: Personnel costs must account for the level of effort required to initiate and complete the mandated Peer-Review Process. See the Detailed Peer-Review Budget for Peer-Review-Related Costs section for additional instructions.

B. Consultant Costs

- Consultant costs apply to those individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives must be included in the budget as consultant costs.
• Provide the total cost of the consultant(s), as well as name(s), expected number of hours, and hourly rate.
• Include the daily consultant fee, nature of the consulting effort, and the reasons that the proposed project requires consultants. Note any overlap in duties with personnel.
• Consultant costs must be reasonable and justified.

C. Supply Costs

• Supplies must be directly allocable and allowable to the proposed project, and not be part of general or administrative use. Supplies are consumable items that are used on a regular basis or other tangible items that do not meet the definition of “equipment.” Include the category of supplies needed and the cost for each.
• Tangible items with per-unit costs of $5,000 or more are considered equipment and cannot be accounted for under this category.
• Indicate general categories such as mailings, printing, lab, and equipment with less than $5,000 per-unit costs. Provide detailed explanations in the Budget Justification for all costs exceeding $1,000.
• For all supply costs, provide computations for the way that applicants arrived at the specific number.

Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct-cost charges. If these items are proposed as essential for performing the research project, the following must be provided in the Budget Justification:

• Detailed explanation of why purchasing these items is necessary to complete the proposed research project
• Statement verifying that the requested items are not currently available for the PI’s use
• Statement assuring that the items will be purchased in accordance with applicable cost principles
• Items purchased under PCORI-funded projects are not to be used as incentives to recruit or retain graduate students or any other project personnel.

D. Travel Costs

• Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.
• Travel should be devoted to programmatic activities necessary to conduct the project, such as focus groups, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topical areas of the project may also be included, but should be limited in number, and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.
• Travel costs must be itemized per trip and must include the number of trips and a brief description of each one, including the number of people traveling and dates or duration of the stays.
• Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent), or the lowest commercial discount fare. PCORI will not compensate upgrades.
• In the Budget Justification Template, applicants must provide additional detail to explain the
basis for the costs listed and describe how the travel is directly related to the proposed research project and necessary for achieving programmatic objectives.

E. Other Expenses

- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include computer core services, data warehousing, or participant incentives, return of results to study participants, publication, illustration costs, and non-consulting service contracts (when applicable).
- In the space provided, include a detailed explanation in the Budget Justification for items that exceed $1,000. Applicants must provide additional detail for each of these costs.

F. Equipment Costs

- Equipment costs include those for tangible items that have a per-unit cost of $5,000 or more and a useful life greater than one year.
- You must include with the Budget Justification up to three quotes for each item of proposed equipment.
- Costs must be reasonable and necessary for the project.

G. Subcontractor Costs

- This category includes all consortium and contractual costs. The prime awardee must issue a subcontract agreement to a collaborator if the criteria listed below are met:
  - The subcontractor personnel’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  - The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
- Subcontractors must adhere to all PCORI budget guidelines, including allowable and unallowable costs.

H. Indirect Costs

- PCORI limits the total indirect costs to 40 percent of personnel, consultant costs, travel, supplies, and other expenses and on the first $25,000 of each subcontract.
- Applicants that do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant’s federally negotiated, or independently audited, indirect cost rate letter must be submitted if selected for funding.
- If funded, the indirect cost rate submitted at the time of application is what PCORI will utilize during contract negotiations. If there is a change in the indirect cost rate once a project is executed, and the awardee wishes to charge a different rate, they must contact their PCORI Contract Administrator and provide a copy of the new federally negotiated rate or independently audited rate. PCORI may allow a change in the rate charged, but the awardee will need to reallocate within their existing, approved budget. PCORI will not allow additional funds to offset any increases in indirect costs and the rate increase cannot result in a reduction in scope of the approved project.
- While consortium indirect costs must be noted in the prime applicant’s direct cost budget,
consortium indirect costs are not included in the applicant’s direct cost budget cap.

I. Engagement Costs

- The budget should account for patient and other stakeholder partner (individual and organizational) compensation. For additional guidance, review PCORI’s Compensation Framework.
- Awardees should also consider costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, and incorporating partner feedback. For additional guidance, review PCORI’s Budgeting for Engagement Activities document.

VIII. Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI research contract funds are those that directly support the proposed research project, including collecting and analyzing data and obtaining relevant data sets. Because PCORI primarily funds comparative clinical effectiveness research, the research projects generally involve the comparison of clinical interventions or strategies that are considered to be accepted standard of care and are not experimental or investigational. As a result, when developing proposed Detailed Budgets, it is important for funding applicants to think carefully about which costs derive from, and directly support, the research project, as opposed to those costs that would otherwise be incurred in the course of providing the clinical care and health-related costs around which the research project is organized.

Allowable costs (i.e., those that can be included in a proposed Detailed Budget when applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the research project:

- Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and other stakeholder research study partners) related to their percentage of effort on conducting the research project (such costs may not include personnel who deliver patient care as a component of their participation in the research project)
- Consultant fees
- Travel for mandatory investigator meetings
- Travel that is necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct research expenses
- Indirect costs

A funding applicant must specifically request costs related to conducting the research project through itemization on the Detailed Budget. PCORI will consider this request in the course of making an award. The following principles and requirements generally apply to PCORI’s evaluation of the proposed budget and determination of allowable costs and should guide applicants in preparing their Detailed Budgets:
• Typically, IRB fees are included in an organization’s indirect cost pool. However, PCORI will allow this expense as a direct cost if the costs are not included as part of the indirect cost rate. By submitting the application, the PI and AO certify that their institution treats IRB fees as direct costs, and the fee is allocable to the study. IRB fees are subject to audit.

• 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”). The host healthcare delivery system, third-party payer, product manufacturer, developer of the intervention, or other interested party must cover the patient care costs.

• The willingness of one or more stakeholder groups to cover patient care costs incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project by the stakeholder group. Such commitments also indicate that the stakeholder groups will use the research study’s findings. (Such support by a stakeholder group must be discussed in the application.)

• Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.

• PCORI may consider coverage of the co-payment or co-insurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.

• PCORI will generally cover costs for ancillary tasks necessary to implement or monitor patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project; collecting data pursuant to the research protocol; or collecting and monitoring study subject data that would not normally be performed in the course of patients receiving the patient care evaluated in the research project.

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for the successful execution of the proposed research project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary. For more information, see PCORI Cost Principles.
PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct-cost charges.

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 in the Principles for Consideration of the Full Range of Outcomes Data.