



Cycle 3 2021 Funding Cycle

Limited PCORI Funding Announcement: Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Submission Instructions

Published September 7, 2021

These instructions apply to the Cycle 3 2021 Funding Cycle for the Implementation of PCORI-Funded Patient-Centered Outcomes Research Results limited PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/limited-PFA-implementation-pcor-results-cycle-3-2021>. The Cycle 3 2021 Funding Cycle closes December 7, 2021, at 5 pm (ET).



The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 and reauthorized for an additional 10 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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What has changed for the Cycle 3 2021 funding cycle?

- Updated eligibility requirements for applicants proposing Phased Implementation Projects



I. About These Instructions

This document provides key information to help applicants prepare for and respond to the Implementation of PCORI-Funded Patient-Centered Outcomes Research Results Limited Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA), available at <https://www.pcori.org/funding-opportunities/announcement/limited-PFA-implementation-pcor-results-cycle-3-2021>.

These instructions should answer many questions applicants might have. The following resources are also available:

- See the [Implementation: Limited Competition PFA FAQs](#) for PFA-specific content.
- Visit PCORI's [Help Center](#)¹ for additional applicant resources:
 - PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days before a Letter of Intent (LOI) or application deadline.
 - **For Programmatic Inquiries:** Contact the PCORI Helpdesk via email at disseminationquestions@pcori.org.
 - **For Administrative, Financial, or Technical Inquiries:** Contact the PCORI Helpdesk via email at pfa@pcori.org or phone at 202-627-1885.

It is the applicant's responsibility to submit the LOI and application on or before the deadline. Refer to [PCORI's Policy on Funding Application Submission](#).²

Administrative Considerations

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

All rejection decisions made by the Contracts Management department are final. See [Appendix 2: Administrative Actions](#).

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 of meeting all

¹ Available at <http://help.pcori.org/hc/en-us/>.

² Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.



milestones and deliverables. *Applicants must submit representative budgets and Project 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 (AOs) are advised to carefully review PCORI's standard contract templates provided on the [Awardee Resources](#) page on the PCORI website.³ Note that international awardees will be issued a contract in US dollars. Fluctuations in currency exchange rates will have no bearing on the contract value, nor will adjustments 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 who fail to meet the mutually agreed upon milestones. Applicants' proposed milestones will be finalized in contract negotiations and prior to execution. See PCORI's [Standard Contract Template](#) for more information.

II. Who Can Apply

Evidence Readiness: Applicants must propose a feasible and logical next step(s) that will facilitate real-world uptake and use of clinically meaningful findings associated with a PCORI-funded comparative clinical effectiveness research (CER) study. Only projects proposing to implement or disseminate findings from PCORI CER studies that (1) tested a research hypothesis and (2) evaluated comparative clinical effectiveness of two or more comparators will be considered responsive to this PFA. **Note:** These requirements do not apply to methods studies.

PCORI Research Awardees: Recipients of PCORI research awards, including Broad PCORI Awards, Pilot Projects Program Awards, Targeted PCORI Awards, Pragmatic Clinical Study Awards, and PCORI-funded demonstration projects occurring within the National Patient-Centered Clinical Research Network (PCORnet®) infrastructure (e.g., ADAPTABLE and obesity trials), are eligible to respond to this PFA. Applications associated solely with Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards are not eligible for this limited PFA. **Note:** Although eligible to apply, Pilot Projects must still meet all of the PFA requirements to be considered responsive. Some of the requirements (e.g., evidence readiness) may be difficult for Pilot Projects to satisfy.

Organization: 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 United States applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as the project shows demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research. Organizations may submit multiple funding applications. Individuals are not permitted to apply. For questions about eligibility, contact

³Available at <http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf/>.



disseminationquestions@pcori.org.

Personnel: A Letter of Support is required from the Principal Investigator (PI) of the original PCORI-funded research project if he or she is not the proposed PI of the current application. If the organization submitting an application in response to this PFA is not the original PCORI awardee institution, then the PI of the original PCORI-funded study—or another member of the original research team who played a significant role—must be involved as project personnel in the proposed implementation project.

Timing: Applicants must propose to disseminate or implement PCORI-funded research results that are available at the time of the LOI deadline. Specifically, (1) a draft final research report (DFRR) pertaining to the original PCORI-funded research award must have been accepted for entry into the peer-review process by PCORI, or (2) a manuscript reporting the results of the PCORI-funded study being proposed for implementation must have been formally accepted for publication by a peer-reviewed scientific journal before the LOI deadline for this PFA.

Applicants relying on the submission of the DFRR to meet the above requirement should be aware that PCORI will administratively withdraw LOI submitted before PCORI's acceptance of the DFRR for entry into the peer-review process. Note that it typically takes six weeks to process, revise, and accept **high-quality DFRRs** into PCORI's peer-review process; applicants should plan accordingly.

Applicants relying on the publication of a peer-reviewed manuscript must include formal documentation of acceptance for publication with their LOI submission, or PCORI will administratively withdraw the LOI.

Note: Applicants should refer to the [PFA Overview Table](#) for specific eligibility requirements.

A PI can only submit one LOI per PFA. However, an individual listed as a PI on one LOI may be listed as and serve in another non-PI role (e.g., co-investigator or consultant) on other LOIs within the same PFA, during the same cycle. A PI's project concept may only undergo review in one PFA at a time. A PI wishing to submit an LOI to a particular PFA, who already has a similar project under review in any PFA, *will need to strongly demonstrate that the project being proposed in the new LOI submission is clearly distinct from the application already under review*. This justification must be included in the LOI submission. If a strong enough case is not made during the competitive LOI review process, the LOI will be administratively withdrawn and the application to the other PFA will remain under review.

Similarly, a PI can submit multiple LOIs to different PFAs in a single cycle, but *the PI must strongly demonstrate that the projects are distinct in their aims and approaches*. If a PI submits a single project concept to multiple program PFAs, PCORI reserves the right to administratively withdraw LOIs deemed as duplicate submissions. PIs are encouraged to speak with PCORI staff well in advance of the LOI submission deadline regarding concerns related to potential LOI duplication. This applies to single and dual-PI submissions.

III. How to Apply

Applying for PCORI funding is a two-stage process. To submit an LOI and application (if invited), including all required documents, follow the instructions provided in this document and in [PCORI Online](#).⁴ You

⁴ Available at <https://pcori.force.com/engagement>.



must submit all documents through PCORI Online. Be sure that you are applying to the PFA titled “Limited PCORI Funding Announcement: Implementation of PCORI-Funded Patient-Centered Outcomes Research Results.” Refer to the specific PFA for more information about the review process for LOIs and applications.



Step 1: Register

To apply for PCORI funding, an applicant (Principal Investigator [PI] or PI designee) must register in [PCORI Online](#). To submit an LOI or 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 number](#)⁵ and [an EIN](#),⁶ 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 “Dissemination & Implementation Awards” tile to apply for funding. PCORI strongly recommends that only the PI create the LOI/application record, because whoever creates the record will have permanent access to it in PCORI Online.



Step 2: Submit a Letter of Intent

An LOI is required for new and resubmitted applications. Download the PFA-specific LOI Template from the [PCORI Funding Opportunities](#) page. For formatting instructions, reference Step 4.

To submit an LOI, login to [PCORI Online](#), complete the required fields, and upload the completed PFA-specific LOI Template into the system. For detailed instructions on how to navigate the system, reference [PCORI Online: Pre-Award User Guide for Research Awards](#).⁷



Step 3: Begin Application Process

PCORI will notify applicants by the date specified in the PFA as to whether they have been invited to submit an application.

The application consists of multiple sections in [PCORI Online](#), all of which you must complete before submission. Log in to PCORI Online to view the full list of questions.



Step 4: Format and Complete Required Templates

⁵ Available at <https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html>

⁶ Available at <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>

⁷ Available at <http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf>.



Required templates are available on the [PCORI Funding Opportunities](#) page.⁸ 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 and the original PCORI Contract Number 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:** Use no more than 15 characters per linear inch (including characters and spaces).
- **Line Spacing:** Use single spacing. Use no more than six lines per vertical inch.
- **Text Color:** No restriction. Though not required, black or other high-contrast colors are recommended since they print well and are legible to the largest audience.
- **Margins:** Use at least half-inch margins. The header may fall within the top margin, but the body of the text may not begin closer than a half-inch from the edge of the page.
- **Page Numbers:** Number each page consecutively for each PDF upload. Begin each section of an uploaded document with page 1.
- **Page Limit:** This varies based on the document.
- **File Name Format:** This varies based on the document. Applicants must adhere to the file naming standards noted in the [Submission Checklist](#).
- **References:** PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.

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 5: 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

⁸ Available at <http://www.pcori.org/funding-opportunities/>.



Professional⁹ 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.

Though it may be necessary to letters of support or other signed documents on business letterhead, this is not an acceptable file format for most submission templates. 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 [PCORI Online: Pre-Award User Guide for Research Awards](#).



Step 6: 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 AO to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the 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.

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, PCORI Submission Instructions, or PFAs are not valid issues warranting consideration of a deadline extension. See PCORI’s [Policy on Funding Application Submission](#)¹⁰ for complete information.

V. What to Include



Note: Only applicants selected to submit an application may begin the application process.

You will be notified by the date specified in the PFA, regarding whether PCORI has invited you to submit an application.

Print and complete the provided [Submission Checklist](#) to ensure that the LOI and application are submitted correctly. Download all required templates from the [PCORI Funding Opportunities](#)¹¹ page.

⁹ See adobe.com for more information on Adobe Acrobat Professional.

¹⁰ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

¹¹ Available at <http://www.pcori.org/funding-opportunities/>.

You must submit an LOI before you complete your application. Enter the information into the required fields in PCORI Online.

Download and complete the PFA-specific LOI Template from the [PCORI Funding Opportunities](#) web page. Statements in gray italics provide instructions. Replace the gray italics and any instructional text with your response, but retain the bold headings. **Note that any additional template modifications will result in the disqualification of your LOI.**

The content included in this template will be used as a primary source of information for PCORI's competitive screen process. Focus on including only critical information because space is limited to three pages. Provide a description that allows the program staff to understand the project, including the aims and project design, without reviewing the full application. The three-page limit does not include references. PCORI suggests including all references as in-text citations using AMA citation style, but other citation styles are accepted. (**Note:** All LOI Templates must follow the formatting guidelines provided in [Step 4.](#))

Depending on the type of project you are proposing, complete Section A for Standard Implementation Projects, Section B for Phased Implementation Projects, or Section C for Dissemination Projects. Applicants should delete the sections that they do not complete.

Applicants proposing a Phased Implementation Project must additionally:

1. Have a manuscript reporting the results of the PCORI-funded study being proposed for implementation formally accepted for publication by a peer-reviewed scientific journal before the LOI deadline for this PFA; AND
2. Discuss their Phased Implementation Project proposal with PCORI's Dissemination and Implementation Program at least one week prior to the LOI deadline and receive written approval from PCORI prior to submitting an LOI. Applicants may request a phone call with PCORI staff by emailing disseminationquestions@pcori.org.

LOIs from applicants not meeting these requirements will be administratively withdrawn from the review process.

Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the template (e.g., responses to reviewer comments, Resubmission Letters).

To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: "PI LastName_(five-digit LOI number)_LOI.pdf." [PCORI Online](#) will automatically generate an LOI number, which will be visible at the top of the web page once you save the LOI. Click "Review & Submit" to review your submission, and then click "Submit." Navigate back to the LOI and Application dashboard in PCORI Online, where you can see your LOI number and track your status. Once your LOI is submitted, you cannot edit it.



Proof of Acceptance of PCORI-funded Study Results to Be Implemented

As part of an LOI submission, applicants are required to document that the results of the PCORI-funded study proposed for implementation will be available by the Letter of Intent submission deadline. Specifically, (1) PCORI must have accepted for entry into the peer-review process a DFRR that pertains to the original PCORI-funded research award or (2) a peer-reviewed scientific journal must have formally accepted for publication a manuscript that reports the PCORI-funded study results being proposed for implementation. It typically takes six weeks to process, revise, and accept high-quality DFRRs into PCORI's peer-review process; therefore, applicants should plan accordingly.

Attach official documentation of acceptance by PCORI and/or the peer-reviewed journal, as applicable, to your LOI template and upload it as a single PDF file in PCORI Online.

Resubmission Policy and Letter

Applicants proposing Standard Implementation Projects or Phased Implementation Projects will be allowed **one opportunity** to resubmit an application that completed the merit review process (i.e., the applicant received a summary statement) in a previous cycle but was not funded. Applicants proposing Dissemination Projects will also have one opportunity to resubmit their application.

Applicants may not resubmit an application for a previously submitted and reviewed application until they have received a merit review summary statement (for Implementation Projects) or programmatic feedback (for Dissemination Projects) for the initial submission. All resubmitted applications require the submission of a new LOI that must be administratively and programmatically responsive to the PFA. Resubmitted applications must include a [Resubmission Letter](#), not to exceed two pages. Applications that do not meet these requirements will be deemed nonresponsive and withdrawn from merit review. LOIs that are not invited to submit a full application by PCORI do not count as a submission or resubmission.



Note: To ensure that new LOIs and resubmitted applications are administratively and programmatically responsive, applicants must carefully read and meet all requirements described in the PFA to which they are applying for funding.

PI and Contact Information

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

Principal Investigator

- A. Description
 - The PI is responsible for the project's engagement, scientific, and/or technical aspects.



- 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 or a different role, such as dual-PI, 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 individual 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 project 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 the second PI.
- The PI (or PIs) manages day-to-day project operations.
- The PI (or PIs) acts as the organization's lead project representative.



Note: A [Letter of Support](#) is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI for the current application.

Administrative Official

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 awarded funds 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

PCORI identifies as key personnel 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, consultant) on other applications.
- If applicable, applicants must explain the rationale for including two PIs in the Leadership Plan Template.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See PCORI’s [Glossary](#) for definitions of *consultant* and *subcontractor*.
- Applicants should identify patient and stakeholder partners, whether individuals or organizations, if known. Note that 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 stakeholder partner chooses to remain anonymous, contact pfa@pcori.org for guidance.

After merit review, PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.

If funding is awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post–contract execution.

Application Requirements



The following sections are applicable only if PCORI has invited you to submit a full application. PCORI will notify applicants of this decision via email by the date specified in the PFA. You are invited to submit an application based on the information provided in the LOI.

Any changes to the following require PCORI’s approval:

- PI (Contact PI and second PI)
- Institution
- Implementation approach



- Specific aims

If you need to change any of this information or have any questions, email pfa@pcori.org.

PI and Contact Information

Review the information transferred from your LOI and update as needed.

Project Information

Enter the following information directly into PCORI Online.

Project Summary

Please copy and paste the text from the body of your Project Summary (see [Project Summary Template](#)) into the designated field in PCORI Online. As a reminder, you must also upload your Project Summary as a PDF to the Templates & Uploads section in PCORI Online.

Milestones Template

Applicants must complete the [Milestones Template](#) and upload it as an Excel file, not as a PDF, in PCORI Online, in the designated upload field. Follow the instructions in the template and complete all required sections. For the milestones provided in the template, based on the Milestone—Deliverable Name (Column B) and the 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. Applicants should insert rows for additional milestones, when and where appropriate as they would correspond to the timing of the milestone.

Milestones are concrete, specific, documented activities or accomplishments as well as deliverables due throughout the project. Milestones should be associated with the proposed project timeline and reflect all essential/important activities that you will undertake to accomplish your specific project goals.

As part of Merit Review Criterion 3, Technical Merit, reviewers evaluate the submitted milestone schedule to assess the feasibility of the project plan.

Examples of milestones include, but are not limited to, the following:

- Institutional Review Board approval (if applicable)
- Activities related to the adaptation of findings/interventions from the PCORI-funded study
- Launch of implementation at participating sites/systems
- Data collection (including from focus groups/interviews, surveys, claims data, and the electronic health record)
- Data analysis activities and reporting of evaluation results
- Training activities (e.g., for staff delivering the intervention)
- Documentation of new or revised processes, protocols, or policies that will lead to changes in



practice by those delivering the intervention (e.g., updated clinical procedures/workflows)

- Site visits
- Development and use of educational materials, resources, training manuals, or other materials in your implementation project
- Engagement activities, such as stakeholder/advisory meetings, workshops, and so on
- Accomplishing reach targets

If PCORI funds your application, additional interim and final deliverables may be added to your contract during the contract execution process. Note also that PCORI reserves the right to request additional deliverables during the life of the project, and must approve all changes to milestones requested by awardees.



Note: Milestones must be associated with a timeline and include project objectives that will be accomplished at specific times during the proposed project.

Project Team

Applicants must assemble a team that is suited to complete the work. Applications must demonstrate that the project team's experience, leadership approach, governance, and organizational structure are appropriate for the project and will aid in successfully achieving the project goals.

Applicants will complete and upload two separate key personnel files:

- PI Template (includes Dual-PI information and Leadership Plan, if applicable)
- Key Personnel Template (includes all other key personnel on project, including co-investigators, consultants, or other significant contributors)

For each person listed as key personnel (including PI, dual-PI, co-investigator, consultant, or other significant contributors, as noted in the sections below), complete a Profile/Biosketch section (up to five pages per individual). Note that you may submit the most recently posted National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient and stakeholder partners serving as key personnel may choose to complete the Patient and Stakeholder Partner Profile/Biosketch form in lieu of the Professional Profile/Biosketch.

PI Template

Applicants must complete the [PI Template](#) for the project lead(s). 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 awarded milestones, deliverables, and reports are completed in accordance with the award terms and conditions.

If proposing a dual-PI application, you must designate one 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.

Complete a Profile/Biosketch (up to five pages per individual) for the PIs, and as appropriate the dual-PI. Combine the profile/biosketches and into a single PDF file. The Contact PI profile/biosketch should be the first item in this upload. If applicable, attach the Leadership Plan to this file as the last item in this upload. Upload the file to the designated field in PCORI Online.

Leadership Plan (Required if Proposing a Dual-PI Application)

Applicants proposing a dual-PI application must include a [Leadership Plan](#) (up to five pages). The Leadership Plan must (1) describe the governance and organizational structure of the leadership team and the project; (2) delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual-PI application; (3) discuss communication plans and the process for making decisions on scientific and engagement direction; and (4) describe the procedure for resolving conflicts.

Note: Only the Contact PI may submit the application to PCORI.

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 each individual's previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. You must also describe the backgrounds, relevant experiences, and roles of patient and stakeholder partners.

Project/Performance Site(s) and Resources Template

The [Project/Performance Site\(s\) and Resources Template](#) may not exceed 15 pages. Demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, and on time.

Applicants must provide a description of the facilities they will use during the project, including capacity, capability, characteristics, proximity, and extent of availability to the project.

Project Plan Template

Complete all required sections in the [Project Plan Template](#) and upload the file as a single PDF to PCORI Online. The Project Plan includes the following: Project Strategy, Protection of Human Subjects (if applicable), Consortium Contractual Arrangements, References Cited, and an Appendix (optional).

Project Strategy

In this component of the Project Plan (up to 12 pages), applicants must describe their project strategy and plan in detail and demonstrate how the proposed project responds to this limited PFA.



All applicants should complete Section A of the Project Plan template. If you were invited to submit a proposal for a Standard Implementation Project, please complete Section B of the Project Plan template. If you were invited to submit a proposal for a Phased Implementation Project, please complete Section C of the Project Plan template. If you were invited to submit a proposal for a Dissemination Project, please complete Section D of the Project Plan.

Protection of Human Subjects (if applicable)

In this component (up to five pages), describe the protection of human subjects involved in your project. 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](#),¹² issued by the US Department of Health and Human Services. Refer to the Required Education of Key Personnel on the Protection of Human Subject Participants requirement in the PFA as you complete this section.

Consortium Contractual Arrangements

In this component (up to five pages), describe the proposed projects that subcontracted organizations will perform. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

Keep the following in mind as you complete this section:

- The prime applicant is responsible for the project and must adhere to the contract’s terms and conditions. The prime applicant must negotiate his or her subcontracts accordingly.
- Signed subcontract agreements are not required at the time of application submission to PCORI.
- Submitting an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations involved in the project are aware of your organization’s subcontract agreement policy and are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
- If applicable, subcontract personnel must be included under key personnel.
- Budget information for subcontracted organizations must be included in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

References Cited

This component (up to 10 pages) is included in the Project Plan Template. Throughout the Project Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of 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, the 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 in any section of the

¹² See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.



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 project, so that the 10-page limit is not exceeded. 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 Project Plan Template. Applicants may provide additional materials to support the proposed project (e.g., survey instruments, interview guides). Note that reviewers are not required to review this section during merit review.

Project Summary Template

Complete all required questions in the [Project Summary Template](#) and upload it as a PDF to PCORI Online. The Project Summary should be written in nontechnical language that the general public will understand. PCORI will provide this summary to reviewers during the merit review process. PCORI will post on its website Project Summaries from applications that are awarded a contract. The names of the individuals and organizations that compose the project team will also be posted on PCORI's website, as described in the Key Personnel section above. Your Project Summary should not exceed two pages. Note that you will also be required to copy and paste the text from your Project Summary Template into the Project Summary field on the Project Information tab in PCORI Online.

Please note that not all Project Summary Template questions may apply to dissemination-focused projects; applicants proposing these projects should adjust their responses accordingly.

Budget

Complete all required sections in the [Detailed Budget Template](#) and [Budget Justification Template](#) for the Prime Institution and each subcontractor and upload to PCORI Online. Do not upload separate budget files for the prime applicant and/or subcontractors; instead, include all Detailed Budget files within the same upload. For the Cycle 3 2021 Limited Competition PFA, the prime institution and all subcontractors will use the same Detailed Budget Template.

Co-Funding

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the project that advances PCORI funding objectives, you may propose to do so in an LOI and, if invited, submit an application. We recommend that you speak with a Program Officer in advance.

Detailed Project Budget for Each Year of the Project Period

For each program year, enter a complete Detailed Budget into the template for the prime institution. For example, if your project lasts two years, the prime institution must complete a Detailed Budget for Year 1 and for Year 2. The subcontractor must follow the same process and complete a Detailed Budget for each year of the proposed project in the corresponding template.



You must enter all personnel information in the Project Personnel tab that corresponds to that year in the Budget tab. The applicant may add additional rows for personnel as needed. Following the example of a one-year project, applicants may delete the unused Year 2 Detailed Budget tabs. However, applicants may not add additional years. Maximum project periods are stated in each PFA.

If you are proposing a **Phased Implementation Project**, utilize tabs 1-3 (Years 1-3) for the Phase 1 budget, as applicable. Begin the Phase 2 budget on tab 4 (Year 4). Phase 1 may not exceed 33 months and \$1.5M in total direct costs. Phase 2 may not exceed 33 months and \$3M in total direct costs. Applicants may not enter more than 12 months' worth of budget information in any tab. Based on these instructions, PCORI understands that applicants with shorter project periods may have empty tabs. Applicants should not delete these tabs. For example, if an applicant is proposing 24 months for Phase 1, then the Year 3 tab will not have any data, and the applicant will begin their Phase 2 budget in the Year 4 tab. Note that your proposed project must be within the maximum project period as stated in the PFA.

Note the following:

A. Personnel Costs

- *Personnel Costs*: These 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 considered 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 1: 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 with [the Budget Justification](#).
- *Level of Effort*: Personnel who contribute to a PCORI-funded research project are expected to monitor their total percentage of effort across all 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. Effort must be reported by the percentage of time over the course of the project year. If salary support is not being requested, use \$0 for the base salary.
- All personnel who dedicate effort to the project must be listed in 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 Templates. Describe the individual's specific functions in the Budget Justification Template. Explain 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 be assessed only 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 upload, following the Budget Justification, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

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 the name(s), expected number of hours, and hourly rate.
- Include the daily consultant fee, consultant travel expenses, nature of the consulting effort, and reason(s) that the proposed project requires consultants. Note any overlap in duties with personnel.
- Consultant costs must be reasonable and justified within the Budget Justification.
- Include Letters of Support from each consultant, verifying the work to be performed and how the negotiated rate was established. See the [Letters of Support](#) section for more detailed information.

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 cost. Provide detailed explanations in the Budget Justification for all costs that exceed \$1,000.
- For all supply costs, provide computations for how 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 you propose these items as essential for performing the project, you must provide the following in the Budget Justification:

- Detailed explanation of why purchasing these items is necessary to complete the proposed project
 - Statement verifying that the requested items are not currently available for the PI's use
 - Statement assuring that you will purchase the items 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 related to the topical areas of the project may also be included, but they 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 the trips, 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, 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, participant incentives, publication costs, illustration costs, and non-consulting service contracts (when applicable).
- In the space provided, include a detailed explanation for all costs that exceed \$1,000. Applicants must provide further detail in the Budget Justification 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.
- 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 these criteria 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, personnel) at his or her own organization when working on the PCORI-funded project.
- State in the Budget Justification why each subcontractor was selected. Provide detail on his or her specific role and the aim or deliverable her or she will be supporting for the 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 with the application. Include these copies in a single file with the Budget Justification.
- If funded, the indirect cost rate submitted at the time of application is what PCORI will utilize during contract negotiations. If a change in the indirect cost rate occurs once a project is executed, and the awardee wishes to charge a different rate, the awardee must contact its 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 its 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.

Budget Justification Template

Complete a [Budget Justification Template](#) for the prime applicant and each subcontracted organization for the entire Project Budget for all research and upload as a single PDF into PCORI Online.

If you are proposing a Phased Implementation Project, please ensure that the costs related to each Phase are specified and explained in the Budget Justification document.

Provide sufficient detail to explain the basis for costs, the reason that 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 and any other engagement costs (e.g., travel, meeting costs, training, other costs associated with convening patients and stakeholders). Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and stakeholder engagement. This person must be listed as a full-time equivalent under personnel, consultant, or subcontractor costs.

Provide detail to explain the basis for travel costs, and describe how the travel is directly related to the proposed project and necessary for achieving programmatic objectives.

Describe the specific role and tasks each project team member will perform and the impact on the Project Plan. PCORI will evaluate each member’s contribution, as listed in the Budget Justification, to validate meaningful contributions and assess whether overlap in responsibilities occurs. Provide a clear distinction between individuals who should be classified as key personnel and those who should be classified as “other” personnel.

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

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

Letters of Support



A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application.

Save all Letters of Support as a single PDF file and upload it to PCORI Online, 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 merit reviewers and PCORI staff. Reviewers are asked to consider the Letters of Support as outlined in the template and in this guidance. Failure to assemble the letters properly may result in the reviewers missing key information. If this occurs, PCORI will not send the application for re-review because it will be deemed an error in application assembly, not an error in review.



All Letters of Support must be addressed to the PI and demonstrate the commitment of relevant key personnel and participating implementation sites/systems, as well as the relevant partners/organizations (e.g., dual-PIs, co-investigators, consultants, patient and stakeholder partners, implementation sites/systems, stakeholder organizations) whose support will be critical for ensuring successful use of the intervention (and overall implementation of the program) during the proposed project. Letters of Support must clearly reflect the involvement and material contribution that the signatory parties will provide, and also confirm the commitment of collaboration.

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

Letters of Support must be organized as follows:

- **Letter of Original PI Support (if applicable):** A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application. Letters from the original PCORI-funded PI must describe his or her support for the proposed approach and team for implementing (or disseminating for Dissemination Projects) research findings.
- **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 project; equipment; and other resources available for the project, including staff.
- **Letters of Collaboration, including from Implementation Sites/Systems:** Provide a signed letter from each collaborating individual or organization that will demonstrate the PI has the support or resources necessary for the proposed work. Letters of Support from patient and stakeholder partners must describe clearly their interest and rationale for involvement in the implementation effort, as well as their role and specific project responsibilities. Include a Letter of Support for each consultant who verifies the work to be performed and their negotiated rate.
- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources (if applicable):** If the proposed plan involves access to patient populations, data sets, or additional resources, include a Letter of Support that confirms such access, signed by the individual with approval authority. If you cannot confirm access 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 resources.

List all letters in the [table](#) (adding rows as needed) and include the page number for each letter in the single PDF file.



Appendix 1: Allowable and Unallowable Costs

Allowable costs (i.e., those costs 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 project investigators and other research project staff (including engaged patient and stakeholder project partners) related to their percentages of effort on conducting the project. (Such costs may not include personnel who deliver patient care as a component of their participation in the project.)
- Consultant fees
- Travel for mandatory investigator meetings
- Travel that is necessary to conduct the project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct expenses
- Indirect costs

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for the successful execution of the proposed project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary. For more information, please see [PCORI Cost Principles](#).

Allowable Costs			
 PERSONNEL SALARIES & BENEFITS	 TRAVEL COST	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS
 CONSULTANT FEES	 EQUIPMENT	 SUPPLIES	 OTHER

Commonly Disallowed Costs	Unallowable Costs		
 DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)	 ADVERTISING	 DONATIONS	 INTEREST OF BAD DEBTS
 DOCKING STATIONS	 EXCESSIVE AIRFARE	 FUNDRAISING	 ENTERTAINMENT
 DOUBLE MONITORS	 ALCOHOLIC BEVERAGES	 PERSONAL EXPENSES	 LOSSES ON OTHER GRANTS
 ELECTRONICS PROTECTION PLANS	 ALUMNI ACTIVITIES	 STUDENT HOUSING AND STIPENDS	 MEMBERSHIPS
 OFFICE FURNITURE	 VISAS	 TUITION	 LOBBYING
 REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD			 RENT

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.



Appendix 2: Administrative Actions

Applicants that fail to submit required documents or adhere to administrative requirements may be rejected from the merit review process. The chart below explains the reasons for rejection, modification, and appended requests.

Automatic Rejection	Modification by PCORI	Appended upon PCORI's Request*
<p>An application or LOI will be automatically rejected if any of the following apply:</p> <ul style="list-style-type: none"> • Exceeds the specified period of performance outlined in the PFA • Exceeds the maximum budget specified in the PFA • Has adjusted margins or font size (LOI) • Does not have (1) a draft final research report pertaining to the original PCORI-funded research award accepted for entry into the peer-review process by PCORI, or (2) a manuscript reporting the PCORI results being proposed for implementation formally accepted for publication by a peer-reviewed scientific journal (LOI) • Does not include or has an incomplete Project Strategy • Proposes passive dissemination as its primary project goal 	<p>PCORI will modify an application by removing all pages that exceed stated limits.</p>	<p>Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones.</p>

* PCORI will not accept requested documents submitted more than one business day after initial request.