Cycle 2 2020 Funding Cycle
COVID-19 Targeted PFA

PCORI Submission Instructions

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These instructions apply to the Cycle 2 2020 Funding Cycle for the COVID-19 Targeted PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at pcori.org/apply. The Cycle 2 2020 Funding Cycle closes May 26, 2020, at 5 pm (ET).
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 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.

Patient-Centered Outcomes Research Institute
1828 L St, NW, Suite 900
Washington, DC 20036
Phone: 202-827-7700
Fax: 202-355-9558
Email: info@pcori.org

Follow us on Twitter: @PCORI
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I. About These Instructions

This document provides key information to help researchers prepare for and respond to the Cycle 2 2020 Funding Cycle for the COVID-19 Targeted PCORI Funding Announcement (PFA).

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 application process.
- See PCORI’s COVID-19 Targeted PFA FAQs for specific questions about this funding opportunity.
- Visit PCORI’s Help Center2 for additional applicant resources.
  - PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to the application deadline.
  - 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.

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 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 Contract 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 milestones and deliverables. Applicants must submit representative budgets and Research Plans that

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/.
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.¹ 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 that 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

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 US applicant organizations. Organizations may submit multiple funding applications. Individuals are not permitted to apply. If you have questions about eligibility, contact 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 US healthcare system and US 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 US-based organization.

A prime award contract to a non-US-based organization should be carefully justified and preferably include a key US-based organization and co-Principal Investigator as a subcontractor. In assessing whether a research award can be made to a non-US 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 US 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-US research organizations.
- The proposed study must demonstrate meaningful effort and involvement of US organizations and investigators with pertinent expertise and experience to contribute to the project.

engagement plan for the proposed study should also adequately and sufficiently include US patients and stakeholders and have clear relevance to the US healthcare system.

**Note:** In general, a Principal Investigator (PI) can submit only one application per PFA. Moreover, an individual listed as a PI on one application may be listed as and serve in another role (e.g., co-PI, co-investigator, or consultant) on other application within the same PFA during the same cycle. This applies to single- and dual-PI submissions.

### III. How to Apply

To submit an application, including all required documents, follow the instructions provided in this document and in PCORI Online. All documents must be submitted through PCORI Online.

#### Step 1: Register

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 number and an EIN, 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: Begin Application Process

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.

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

#### Step 3: Format and Complete Required Templates

Required templates are on the PCORI Funding Opportunities webpage. Find the PFA to which you are

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5 Available at https://pcori.force.com/engagement.
8 Available at http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf.
9 Available at http://www.pcori.org/funding-opportunities/.
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 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 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. Refer to 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.

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**Step 4: Upload Required Documents**

Follow the Submission Checklist included in these guidelines to enter required information. Upload required documents to PCORI Online in the correct order. When instructed, use Adobe Acrobat Professional10 to combine documents into a single PDF file for upload. Within the Templates & Uploads

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

**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 for complete information.

**V. 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 web page.

**Principal Investigator and Contact Information**

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

**Principal Investigator (PI)**

A. Description

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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/.
• 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 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 No. 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

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.
• 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 “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 per Appendix 3. (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.)
• 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 awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post-contract execution.

VI. Application Requirements

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:
  o 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
  o 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.
  o 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
  o 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
  o 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., EHR 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 PCOR 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**

**Budget**

Complete the [Detailed Budget Template](#) for the Prime Institution and each Subcontractor, the [Budget Justification Template](#) for the Prime Institution and each Subcontractor, and upload it to PCORI Online in their designated fields.

**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 study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a Program Officer in advance.
Detailed Research Project Budget for Each Year of the Research Project Period

Complete the Detailed Budget Template and Budget Summary pages (included in the Detailed Budget Template) for the Prime Institution and Subcontractor, combine into one PDF and upload into PCORI Online in its designated field.

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.

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 Templates. 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 Template, 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 within the Budget Justification Template.

• A Letter of Support from each consultant, verifying the work to be performed and how the negotiated rate was established will be requested if the application is under review for funding (post-merit review).

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 Template 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.
- State in the Budget Justification why each subcontractor was selected. Provide detail on their specific role and the aim or deliverable they will be supporting on 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 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.

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 activities and/or meeting costs, and incorporating partner feedback. The documentation and analysis of innovative engagement approaches also may be included. For additional guidance, review PCORI’s Budgeting for Engagement Activities document.

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 (Board) adopted the Process for Peer Review of Primary Research and Public Release of Research Findings.\(^\text{13}\)

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 will be completed in the Prime Institution’s Detailed Budget and the Subcontractor’s Detailed Budget, as needed. Note that the Total Budget will include the Peer-Review Budget and the Research Project Budget when determining compliance with the Maximum Project Budget in the PFA.

- The DFRR is expected to 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 6-12 months of submission (following necessary revisions).
- Costs associated with the Peer-Review Process are limited to 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.
- A Budget Justification must be included for the Peer-Review Budget. 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.
- The Budget Summary must include the Peer-Review Budget.

Budget Summary for Entire Project

A Budget Summary page for the entire project must be completed in the Prime Institution’s Detailed Budget. Review this information prior to submission. See Appendix 1: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI funding.

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Budget Justification Template

Complete a [Budget Justification Template](#) for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget for all research- and peer-review-related costs. Provide sufficient detail to explain the basis for costs, the reason 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 other stakeholder partners, costs of patient and other stakeholder expenses, project staff, engagement activities and/or meeting costs, incorporating partner feedback, and costs associated with the return of aggregate study results to study participants. Also include information about costs related to documenting and analyzing innovative approaches to engagement and effects on the project, if applicable. Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and other 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.

Describe the specific role and tasks each research team member will perform, along with 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 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 research project. Include funding amounts and the period during which 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.
Research Plan Template

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, Dissemination and Implementation Potential, Return of Aggregate Results, Project Plan and Timeline, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, and an optional Appendix.

Research Strategy

In this component of the Research Plan (up to 5 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) Research Question, (B) Significance, (C) Study Design or Approach, (D) Engagement Approach, (E) and Research Team and Environment, and (F) Budget and Duration.

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

- **Addressing a decisional dilemma meaningful to patients.** 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 medication, surgical approach, or care delivery strategy to treat a condition or manage a specific population—is important to patients. Document the uncertainty that patients and other 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. If the existing evidence base regarding the intervention(s) for COVID-19 is limited, as might be expected, it is acceptable to justify the sample for a particular intervention in a different disease where some theoretical and/or biological propositions for its use for COVID-19 may be justified.

- **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 (e.g., PCORnet, the National Patient-Centered Clinical Research Network),
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. In preparing the proposal, applicants should refer to PCORI’s Methodology Standards, as they will be asked to demonstrate how the study adheres to these standards during contract negotiation and execution.

- **Engagement with patients and other stakeholders.** Applicants should describe their initial ideas for gaining input from patients and other stakeholders at key decision points during the study. Applicants have the option of including plans for documenting and analyzing innovative engagement methods that will be used. A finalized plan (“Updated Engagement Plan”) that details the research partners, activities, and engagement methods will be required within two months after contract execution if funded. (References: Engagement Resources, Engagement in Health Research Literature Explorer, Updated Engagement Plan, PCORI Methodology Standards on Patient-Centeredness)

- **Research Team and Environment.** 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. Describe the following:
  - How and why those research sites were selected
  - The resources, facilities, support, and collaborations available to ensure the project’s success
  - Access to and support of patient groups

Provide all key personnel, professional and partner profiles/biosketches, and detailed site descriptions within the People and Places Template as a separate PDF upload.

**Dissemination and Implementation Potential**

In this component, applicants should describe specific opportunities as well as possible barriers to disseminating and implementing their work in other settings specific opportunities as well as 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.

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 Letters of Support PDF document as the last item.
Note: For this PFA only, applicants’ responses to both the Dissemination and Implementation Potential and the Return of Aggregate Study Results components are limited to one-page total. It is up to the applicant how that one-page is used to address the requirements of those two components.

Return of Aggregate Study Results

In this component, 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 distribution the study results to study participants by email, mail, newsletter, or other approaches.

In the Prime Institution’s Detailed Budget and in Budget Justification, applicants should specify costs associated with this return of results to study participants. Studies with fewer than one thousand participants may budget up to $2,500. If this amount does not suffice for studies needing to return results to a larger number of participants, they may propose a larger amount with justification. Please note that the costs associated with the return of results must be included as part of the Total Budget (in the Prime Institutions’ Detailed Budget) 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 return of results is not possible. For example, this provision does not apply to studies that use secondary data or when participants are anonymous. If applicable, applicants’ response to this section should address why the return of results is not feasible.

Project Plan and Timeline

In this component (up to 1 page), provide a brief project plan with an accompanying timeline for the completion of the research project within the project duration being requested. There is no required format for this plan, but a timeline or Gantt chart is appropriate. Be sure to include all major components which could include a list of major activities, milestones, and deliverables and estimated time periods for each (e.g., recruitment start and end date).

Protection of Human Subjects

In this component (up to one page), describe the protection of human subjects involved in your research. PCORI follows the Federal Policy 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, \(^{14}\) which was 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 section in the PFA as you complete this section.

**Consortium Contractual Arrangements**

In this component (up to five pages), describe the proposed research 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, include subcontract personnel under key personnel.
- Include budget information for subcontracted organizations in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

**References Cited**

This component (up to 5 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. 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 10 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*

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\(^{14}\) See http://grants.nih.gov/sites/default/files/supplementalinstructions.docx.
that reviewers are not required to review this section during merit review.

People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the People and Places Template. Complete a Profile/Biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-PI, dual-PI, co-investigator, consultant, or other significant contributors), copying the tables provided in this section as needed. 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. 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. For patient and stakeholder partners, describe the backgrounds, relevant experiences, and proposed 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.

Project/Performance Site(s) and Resources

This component (up to 15 pages) is in the People and Places Templates. 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.

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

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.

Applicants proposing a dual-PI application, must include a Leadership Plan (up to two* pages) as the first section of the People and Places Template. The Leadership Plan must (1) describe the governance and
organizational structure of the leadership team and the research 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.

*This document originally stated the Leadership Plan page limit was five pages. It was corrected to two pages on May 13, 2020.
Appendix 1: 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.
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.

<table>
<thead>
<tr>
<th>Automatic Rejection</th>
<th>Modification by PCORI</th>
<th>Appended upon PCORI’s Request*</th>
</tr>
</thead>
<tbody>
<tr>
<td>An application will be automatically rejected if any of the following apply:</td>
<td>PCORI will modify an application by removing all pages that exceed stated limits.</td>
<td>Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones.</td>
</tr>
<tr>
<td>• Exceeds the specified period of performance outlined in the PFA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Exceeds the maximum budget specified in the PFA</td>
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<tr>
<td>• Has adjusted margins or font size</td>
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</tr>
<tr>
<td>• Does not include or has an incomplete Research Strategy</td>
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</tbody>
</table>

*PCORI will not accept requested documents submitted more than one business day after initial request.
Appendix 3: Additional Materials Needed for Applicants Under Consideration for Funding Post-Merit Review

Due to the uniquely fast timeline of this funding opportunity, PCORI has modified requirements and reduced the number of documents required at the time of application submission.

Upon completion of merit review, PCORI will contact applicants being considered for funding via a formal PCORI Information Request and request the following documents:

- Milestone Template
- Methodology Standards Checklist
- Letters of Support

Applicants may submit these templates during the application stage via PCORI Online in the designated upload field but are not required to do so. However, should an application be under consideration for funding (post-merit review), they will be required. Therefore, PCORI encourages all applicants to download and complete these templates while waiting for PCORI's notification.

Please note that a PCORI Information Request should not be construed as approval of the application; instead, it helps inform our decision on the final set of applications to recommend for funding.

Methodology Standards Checklist

Complete Column D of the checklist, using the drop-down menu options to indicate whether each PCORI Methodology Standard applies to their proposed research. Complete the subsequent columns, as appropriate, following the instructions in the checklist. If the standard applies, in Column E provide the page number(s) of your Research Plan where the text illustrates how you addressed the standard. Last, in Column F, indicate whether your study may deviate from the standard and provide a rationale. Indicate “Not Applicable (N/A)” if particular standards are not applicable to your study. Refer to the PCORI Methodology Report for explanations of the standards.

If submitted during the application phase, upload it to PCORI Online as an Excel file in the designated field. If submitted in response to a PCORI Information Request, attach it as an Excel file.

Milestones Template

Follow the instructions in the Milestone 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. Insert rows for additional milestones, when and where appropriate as they would correspond to the timing of the milestone.

Milestones are concrete, specific events or accomplishments that are documented by deliverables, associated with a timeline, and must include project objectives that will be accomplished at specific times during the proposed project. PCORI encourages applicants to provide three to six milestones per...
six-month reporting period, though there is no minimum or maximum. Each reporting period should include the major milestones reflecting the research activities and only those activities that the PCORI contract supports. Some examples of milestones include reaching specific patient accrual targets, developing a survey, commencing the intervention, and establishing project-specific databases.

Interim and final deliverables will be negotiated and 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.

If submitted during the application phase, upload it to PCORI Online as an Excel file in the designated field. If submitted in response to a PCORI Information Request, attach it as an Excel file.

**Example Milestones**

Milestones are significant events, deliverables, tasks, or outcomes that occur over the course of each project and signify study progress. The completion of each milestone is intended to mark progress toward the project goals and to ensure that the project is on schedule and likely to be completed within the contract period. As part of Merit Review Criterion 3, reviewers evaluate the submitted milestone schedule to assess the feasibility of the study plan.

The following are examples of milestones and deliverables to be submitted to PCORI. You may reference this list as you complete this section of your application. The nature of these milestones will vary depending on the design of your study (e.g., observational cohort versus randomized controlled trial), and the timing will depend on whether you are submitting an application for a small or large award.

**Required:**

- Awardees must submit a PCORI Progress Report in PCORI Online at least every six months.
- A final progress report is due at the end of the period of performance.

Within first two to nine months of an executed contract:

- Develop, finalize, and submit copy of IRB-approved study protocol in accordance with the PCORI Methodology Standards.
- Submit IRB approval in PCORI Online (continuing approval submitted annually).
- Select and register project at appropriate site for the study design (ClinicalTrials.gov, RoPR, or other as approved by PCORI before study start date). This must occur prior to initiation of recruitment.
- Submit updated Data Safety and Monitoring Plan. Refer to the **PCORI Policy on Data Safety and Monitoring Plans for PCORI-Funded Research**. This must occur prior to initiation of recruitment.
- Submit Updated Recruitment Plan. This must occur prior to initiation of recruitment.
  - Elements in the recruitment plan should, at a minimum, include the following: timeline; total target sample size for primary analysis; name and number of study sites; historical patient volume and estimated eligible N across study sites; estimated yield/consent; estimated loss to follow-up, attrition and/or cross-over (as applicable); and estimated monthly enrollment.
• Submit Updated Engagement Plan within 2 months of contract execution
• Begin recruitment: Site(s) activated and screening for study enrollment within the first 3 months.
• Enroll first patient. From this point forward, submit monthly enrollment update to PCORI including cumulative and interval recruitment, accrual, and retention for the overall study (e.g., number eligible, approached, consented, enrolled, retained).
  o Monthly enrollment updates are not required in the milestone schedule, but awardee must include milestones to enroll and retain 25, 50, 75 and 100 percent of targeted sample size (include target N of patients per reporting period) throughout the duration of the project.
• Submit 100 percent of the IRB approvals across sites to PCORI.

Within the first 12 to 15 months of an executed contract:
• Submit status report detailing executed subcontract agreements across sites.
• Seventy-five percent of the sites must have started recruiting patients.
• The 100 percent cumulative enrollment target must be met within the first 12 months.
• Primary Completion Date
  o This follows the NIH definition pertaining to the primary outcome. The NIH definition of Primary Completion Date is the date when the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. This milestone should be relocated so that complete data collection for the primary aim is completed within the first 12 months of contract. This date must precede the estimated submission date of the Draft Final Research Report (DFRR).
  o An estimated Primary Completion Date must be provided when registering the study in ClinicalTrials.gov. For studies that are not clinical trials or non-prospective observational studies registered on ClinicalTrials.gov, the Awardee and PCORI shall agree on a Primary Completion Date as a milestone within the first 12 months of contract execution.

Remainder of Contract:
• Research deliverables and findings (e.g., instruments, data dictionaries, abstracts and manuscripts)
• Completion of Data Collection for All Study Aims
  o Completion of Data Collection milestone should ideally occur before Completion of Data Analysis for All Study Aims milestone; however, may be the same date.
• Completion of Data Analysis for All Study Aims
  o Completion of Data Analysis for All Study Aims Date must be on or before date of submission of Final Progress Report. It should be scheduled to be due three (3) months prior to submission of DFRR.
• Results submitted to ClinicalTrials.gov or applicable database
  o Awardee ensures results are submitted to ClinicalTrials.gov or another database.
This should occur no later than 12 months from Primary Completion Date for applicable studies. PCORI encourages and recommends the first submission to clinicaltrials.gov be within 6 months of Primary Completion Date, as applicable.

For ClinicalTrials.gov, the generated tables are a required section in the DFRR. Results must be submitted to ClinicalTrials.gov no later than submission of the DFRR.

- Last Submission of Results to ClinicalTrials.gov (if applicable)
  - The specific timing of multiple milestones for submissions to ClinicalTrials.gov may vary, depending on the number of study aims (some milestones may occur after the milestones for Completion of Data Collection for All Study Aims and Completion of Data Analyses for All Study Aims). The complete and final submission of results to ClinicalTrials.gov must appear one month before the DFFR Submission milestone.

- DFRR Submission
  - This date should be 3-4 months after the completion of Data Analysis for All Study Aims milestone. Submit DFRR according to these instructions.

- DFRR Revisions
  - This date should be 6 months after "Draft Final Research Report Submission.” Upon receipt of written summary, and as applicable, PI will make revisions and submit revised DFRR and disposition of comments table for acceptance in accordance to PCORI policy and process.

If awarded, a contractual milestone schedule will be negotiated and finalized with the PCORI project team. Additional reporting, such as monthly enrollment updates, may be required.

**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 merit reviewers and PCORI staff.

All Letters of Support must be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., dual-PI, co-PI, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of Support for personnel who are not contributing in a substantive, measurable way to the project’s scientific development or execution should not be submitted. 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.

Applicants selected for funding will be required to submit applicable Letters of Support prior to contract
execution.