



PCORI Application Guidelines:

The Natural Experiments Network: A Collaborative Initiative

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These guidelines apply to the Natural Experiments Network limited PCORI Funding Announcement (PFA) that closes on September 16, 2015, at 5:00 p.m. (ET). Funding announcements, templates, and other resources are available at <http://www.pcori.org/2015-Natural-Experiments-Network>.



About PCORI

The Patient-Centered Outcomes Research Institute (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, caregivers, and the broader healthcare community.

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, clinicians, purchasers, and policy-makers 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."

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I. About These Guidelines

This document provides key information to help researchers prepare and respond to the limited PCORI Funding Announcement (PFA) [The Natural Experiments Network: A Collaborative Initiative](#).

These guidelines will answer many questions you might have, but other resources are also available:

- PCORI's [Applicant FAQs](#)¹ cover common questions about PCORI and the application process.
- Visit PCORI's [Help Center](#)² for additional applicant resources.
- **Programmatic Inquiries:** Please contact the PCORI helpdesk via email (sciencequestions@pcori.org), via phone (202-627-1884) or online (<http://www.pcori.org/PFA/inquiry>). PCORI will provide a response within three business days.
- **For Administrative, Financial, or Technical Inquiries:** Please contact the PCORI helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI helpdesk (202-627-1885).

It is the applicant's responsibility to submit the application on or before the deadline. Please refer to [PCORI's Policy on Submission of Research Contract Applications](#).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 Application Guidelines. Applicants who fail to submit the required documents or who exceed the stated page limits may be rejected from the merit review process.

All rejection decisions made by the Contracts Management and Administration department are final. Please email pfa@pcori.org with any formatting or administrative compliance questions to ensure that your Letter of Intent (LOI) or application will not be deemed noncompliant once submitted to PCORI. See [Appendix 3: Administrative Actions](#).

Unless otherwise stated within the Application Guidelines, all submissions 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 issues contracts, not grants, to fund and administer meritorious research. PCORI funds projects that demonstrate the highest probability of being completed on time and within budget, and meeting all

¹ Available at pcori.org/funding-opportunities/applicant-faqs

² Available at <https://help.pcori.org/hc/en-us>

³ Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/



milestones and deliverables. *Applicants should submit representative budgets and research plans that will realistically allow the project to conclude within the approved period of performance.*

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract period. To review an example of a sample contract terms and conditions used by PCORI in the past, see [PCORI Contract for Funded Research Projects](#).⁴ PCORI's funding contract with the selected awardee institution for the PPRN Research Demonstration Projects will be based on PCORI's sample contract terms and conditions, and will have additional provisions appropriate for the specific research project, including its use of PCORnet.

II. Who Can Apply

For this limited PFA, PCORI is soliciting applications only from Clinical Data Research Networks (CDRNs) that are currently funded by PCORI and which have applied to the Centers for Disease Control and Prevention (CDC) funding opportunity "Natural Experiments of the Impact of Population-targeted Health Policies To Prevent Diabetes and its Complications" (RFA-15-001). Applicants that receive funding from the CDC under the CDC funding opportunity are ineligible for this PFA and will have their application withdrawn. To be eligible for this opportunity applicants must submit the following:

- A copy of the full application submitted to CDC in response to the CDC funding opportunity RFA-15-001
- A copy of the summary statement from the CDC's technical review
- A copy of the score given by the CDC during technical review

The awardee institutions will assume responsibility for the study, including dispersion of funds to any and all necessary subcontractors needed to conduct the study. If you have questions about eligibility, please contact pfa@pcori.org.

III. How To Apply

To submit an application, including all required documents, please follow the instructions provided in these guidelines and in [PCORI Online](#).⁵ All documents must be submitted through PCORI Online. Please refer to the specific Natural Experiments Network PFA for more information regarding the review process of applications.

⁴ Available at <http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf>

⁵ Available at pcori.fluxx.io.



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](#)⁶ and/or [an EIN](#), if applicable.⁷



Step 1: Register

To apply for PCORI funding, an applicant (Principal Investigator [PI] or PI designee) must register in PCORI Online. A name, an email address, a password, and a security question and answer are required to register. The email address provided will be the username. PCORI strongly encourages only the PI to create the application, as whoever creates the application will have permanent access to it.



Step 2: Begin Application Process

The application process consists of five sections within PCORI Online, all of which must be completed prior to submission. Please log in to PCORI Online to view in the Project Information tab the full list of questions that requires completion before submission. It is recommended that you log in early in the application development process to become aware of the required questions.



Step 3: Format and Complete Required Templates

Required templates are available in the [PCORI Funding Center](#).⁸ Download the correct PFA-specific templates located in the Applicant Resources section, as they are unique to this funding announcement. Please note:

- Do not reorganize sections within the templates.
- Do not alter header questions of the templates within your submission.
- You may delete instructional text.

All required documents must be formatted as follows:

- Header: Include the PI's full name on every page in the top left corner of the page header.
- Margins: Use at least half-inch margins. The header may fall within the top margin, but the body of the text should not begin closer than one half-inch from the edge of the page.

⁶ Available at dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/.

⁷ Available at [irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-\(EIN\)-Online](http://irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online).

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

- Font: Use size 11 Calibri for the main body of the text. Figures and captions may be in smaller type.
- Page Numbers: Uploaded documents must be consecutively numbered.
- Spacing: Use single spacing.



Step 4: Upload Required Documents

Follow the [Application Checklist](#) included in these guidelines to enter the required information. Upload required documents into PCORI Online in the correct order. Use Adobe Acrobat Professional⁹ to combine documents into a single PDF file for upload. To upload, select the name of the required document from the dropdown list. For detailed instructions, refer to the Templates and Uploads section of the [PCORI Online User Manual: Submitting an Application](#).



Step 5: Submit for Authorization

Once all required information has been completed and uploaded, click “Submit to AO” 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 prior to the deadline. **The PI should inform the AO when the application is ready for review 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 Center and in the PFA. Deadlines are at 5:00 p.m. (ET) on the due date. If deadlines fall on a weekend or a federal holiday, then the deadline will be the following Monday or the next day after the federal holiday.

System or technical issues with PCORI Online affecting 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 the PCORI Online System, PCORI guidelines, or a specific PFA are not valid issues warranting consideration of

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



a deadline extension. Please see PCORI's [Policy on Submission of Research Contract Applications](#)¹⁰ for complete information.

V. What To Include

Applicants are encouraged to review this entire section. Print and complete the provided Application Checklist to ensure the LOI and application are submitted correctly and completely. All required templates can be downloaded from the [PCORI Funding Center](#).¹¹

¹⁰ Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications

¹¹ Available at pcori.org/apply



Application Checklist

Application	Submission Method	Length/Limit
<input type="checkbox"/> Principal Investigator (PI) and Contact Information	Enter into PCORI Online	N/A
<input type="checkbox"/> Project Information		
<ul style="list-style-type: none"> • Technical Abstract 	Enter into PCORI Online	6,000 characters/spaces
<ul style="list-style-type: none"> • Public Abstract 	Enter into PCORI Online	3,000 characters/spaces
<input type="checkbox"/> Key Personnel	Enter into PCORI Online	As needed
<input type="checkbox"/> Milestones	Enter into PCORI Online	As needed
<input type="checkbox"/> Research Justification Template	Save file as “ResearchJustification_PI Last Name.pdf” and upload as a single file	As noted below
<ul style="list-style-type: none"> • Research Justification 		Five pages
<ul style="list-style-type: none"> • Engagement Plan 		Three pages
<ul style="list-style-type: none"> • Approach to Patient-Centeredness 		Three pages
<ul style="list-style-type: none"> • Dissemination and Implementation Potential 		Two pages
<ul style="list-style-type: none"> • Replication and Reproducibility of Research and Data Sharing 		Two pages
<ul style="list-style-type: none"> • Protection of Human Subjects 		Five pages
<ul style="list-style-type: none"> • Consortium Contractual Arrangements 		As needed
<ul style="list-style-type: none"> • References Cited 		10 pages
<ul style="list-style-type: none"> • Appendix (optional) 		10 pages
<input type="checkbox"/> People and Places Template	Save as “PeoplePlaces_PI Last Name.pdf” and upload	As noted below
<ul style="list-style-type: none"> • Professional Profile/Biosketch 		Five pages per individual
<ul style="list-style-type: none"> • Patient/Stakeholder Partner Biosketch 		Five pages per individual
<ul style="list-style-type: none"> • Project/Performance Site(s) and Resources 		As needed
<input type="checkbox"/> Budget Template	Combine and save as “Budget_PI Last Name.pdf” and upload	As needed

Application	Submission Method	Length/Limit
<ul style="list-style-type: none"> Detailed Budget for Each Project Year (Prime and Subcontractors) Budget Summary for Entire Project Budget Justification (Prime and Subcontractors) Federally Negotiated or Independently Audited Indirect Cost Rate Letter Fringe Benefit Rate Policy Verification Document 		
<input type="checkbox"/> Letters of Support <ul style="list-style-type: none"> Letters of Support Table Letters of Support 	Save as "Letters_PI Last Name.pdf" and upload as a single file	As needed
<input type="checkbox"/> Full CDC Application <ul style="list-style-type: none"> A copy of the full application submitted to CDC in response to the CDC funding opportunity RFA-15-001 	Save as "CDCApplication_PI LastName.pdf" and upload as a single file	As needed
<input type="checkbox"/> Summary Statement <ul style="list-style-type: none"> A copy of the summary statement from the CDC's technical review 	Save as "CDCSummaryStatement_PILastName.pdf" and upload as a single file	As needed
<input type="checkbox"/> Score <ul style="list-style-type: none"> A copy of the score given by the CDC during technical review 	Save as "CDCTechnicalScore_PI LastName.pdf" and upload as a single file	As needed

Application Requirements

PI and Contact Information

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

Principal Investigator

A. Description

- Applicants must designate one PI as the primary contact.
- The PI is responsible for scientific or technical aspects of the project.
- Applications can include, in addition to the PI, multiple co-PIs. (Note that only the primary PI's name will be published with the contract if the project is funded.)
- The PI's institution must be the primary institution for the award unless approval was granted before the application deadline.
- Investigators may serve as PI on only one application per cycle for any individual PFA.
- PIs can participate in other applications (from the same or another organization) in a different role, such as co-PI, co-investigator, or consultant.



B. Activities

- The PI assumes responsibility and accountability for research execution, compliance, and organization conduct.
- The PI manages day-to-day operations of the project.
- The PI acts as lead research representative of the organization.
- The PI serves as the PCORI lead point of contact for programmatic matters.

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 the appropriate use of funds awarded and for the performance of 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 required all expenditure reports.

B. Activities

- The FO completes and certifies the required yearly expenditure reports.
- The FO executes accounting of contract funds and submits invoices and payment details.

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 should 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 question(s) and long-term objectives.
- **Study Description:** Provide a detailed description of the study design. Please include, as applicable:
 - Overall study design
 - Main components of the intervention and comparator(s)
 - Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
 - Primary and secondary outcomes
 - Analytic methods

Public Abstract

Provide a description of your project, written in lay language that the general public will understand. Please include the following:

- Description of the problem your project seeks to solve
- Outcomes you hope to achieve
- Brief background on why this project is important to patients
- Explanation of how patients and other stakeholder partners will help make the project successful

This summary should be comprehensible to a variety of audiences and will be reviewed by patient and stakeholder reviewers during the merit review process. Public abstracts from proposals that are awarded a contract will be posted on PCORI's website.



Key Personnel

PCORI identifies key personnel as any individual who is considered critical to the project's scientific development and execution in a measurable way and whose absence from the project would negatively impact the likelihood of success. Note the following:

- Applications can include one PI and multiple co-PIs.
- PIs can serve in other roles (co-investigator or consultant) on up to two other applications.
- Applicants must explain in the Budget Justification the rationale for including a co-PI.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See the [glossary](#)¹² for "consultant" and "subcontractor" definitions.
- Project directors are considered key personnel.
- Anyone who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
- In your application, you will be asked to identify the primary patient and stakeholder partners on the project. PCORI is interested in highlighting the work of key patient and stakeholder partners on research projects. In the event that your project is awarded a contract, the primary patient or stakeholder partner(s) will be named in a public announcement along with the PI and research or academic institution.
- If awarded, PCORI will need to approve additional or replacement key personnel (listed in the submitted application) during contract negotiation and post-contract execution, as detailed in contract terms and conditions.

Milestones

Milestones are completed within PCORI Online. Explain the goals and outcomes accomplished during the proposed project. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They include only activities that are supported by the PCORI contract. Examples of milestones include reaching specific patient accruals, survey development, commencement of the intervention, and establishment of project-specific databases. See [Appendix 1: Example Milestones](#) for a more complete list. Milestones should also include activities dedicated specifically to engagement, such as the recruitment of all patient/stakeholder research partners, results of annual surveys of patient/stakeholder partners, or meeting minutes of patient/stakeholder advisory councils.

The following milestones should be included, as appropriate:

1. Subcontract with a PCORnet data coordinating center (CC), participating clinical data research network (CDRN) and patient-powered research network (PPRN) study sites, and data safety monitoring board, as needed
2. Institutional Review Board (IRB) approval
3. Data cohort identification
4. Minutes of Data and Safety Monitoring Board (DSMB) meetings

¹² Available at <http://www.pcori.org/content/glossary>

5. Start of recruitment (indicate target total)
6. Completion of 25 percent of recruitment
7. Completion of 50 percent of recruitment
8. Completion of 75 percent of recruitment
9. Completion of recruitment
10. Focus group results
11. Interim analyses
12. Final analyses
13. Data sets, analytic data sets, and codebooks
14. Interim progress reports due every six (6) months
15. Interim progress report at one year for administrative review
16. Final report due on the last day of the contract period
17. Copies of submitted and published manuscripts
18. Registration of the trial on clinicaltrials.gov
19. Engagement updates, every six (6) months, noting specific engagement activities that patients/stakeholders participated in during the reporting time period. Examples of engagement activities include describing or summarizing the specific ways in which patient and stakeholders were involved in the development of interventions materials and describing patient and stakeholder involvement and contribution in the early stages of the research project, such as enrollment of research participants, baseline assessments, and the process evaluation component

Interim and final deliverables will be included in your research contract if your proposal is funded. Please note that PCORI reserves the right to request additional deliverables during the life of the project.

Examples of deliverables that may be required following contract execution include, but are not limited to:

- Copies of IRB approval
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- Copies of papers accepted for publication
- Meeting minutes from patient/stakeholder advisory panels, committees, or work groups
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Copies of newsletters highlighting the project from patient/stakeholder partner organizations
- Reports of endorsement of research findings by scientific and consumer groups
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Registration of the trial on clinicaltrials.gov
- DSMB meeting recommendations
- Other documents or materials, as appropriate



Note: Milestones entered into the system should be specific deliverables and attached to a timeline; however, the milestones described within the research strategy should include overall goals that will be accomplished during the proposed study.

Research Justification Template

Complete all required sections in the [Research Justification Template](#) and upload as a single PDF into PCORI Online. The PDF includes: Research Justification, Engagement Plan, Approach to Patient-Centeredness, Dissemination and Implementation Potential, Replication and Reproducibility of Research and Data Sharing, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, and Appendix (optional).

Research Justification

This component (up to five pages), included in the Research Justification Template, addresses the following sections: (A) Background, (B) Significance (C) Research Plan Justification (D) Project Milestones and Timeline, and (E) Research Team and Environment. **Please provide all of the information requested, as outlined in the template.**

Applicants should not rewrite a full research application. Applicants should indicate for each PCORI requirement below where reviewers can find information within their full applications to CDC, which will be submitted with this application.

- In all instances where specific PCORI criteria are listed, your response may simply cite the relevant page number and section of your CDC application.
- If you wish to amplify or otherwise modify your CDC response, you may do so in the same space, ensuring that you do not exceed the five-page limit.

While completing the Research Plan Justification (Section C), applicants must cite PCORI's Methodology Standards.

Adherence to PCORI Methodology Standards

Applicants are required to adhere to the [PCORI Methodology Standards](#)¹³ and accepted best practices. Refer to the methodology report for explanations about the standards and identify which ones are relevant to your study.

Include the relevant methodology standard citations (e.g., "PC-3"), as identified in the PCORI Methodology Report for those standards applicable to your study.

If you have not previously addressed in your CDC application a specific PCORI methods standard that you have identified as relevant to your study, then you must provide an explanation for it in the section indicated on this template.

¹³ Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf



PCORI Methodology Standards include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and relevant to most Patient-Centered Outcomes Research (PCOR) studies.

Researchers should refer to all of these standards when planning and conducting their research projects. These five categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effect

Five other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study. These five categories are:

- Standards for Data Registries
- Standards for Data Networks as Research-Facilitating Infrastructures
- Standards for Causal Inference Methods
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Studies of Diagnostic Tests

These standards should be considered minimal. Additional best practices, including guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application.

All applicants should 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.

Following [PCORI's Methodology Standards](#), cite each relevant standard and provide a brief statement indicating how your proposed research demonstrates adherence to it. Do not address standards that are not applicable to your study. PCORI program staff will review relevant standards and plans for adherence with the research team during the contract negotiation phase for proposals that are awarded funding.

Engagement Plan

The engagement plan (up to three pages) follows PCORI's [Engagement Rubric](#), which should be used as a guide. Before completing this section of the research strategy, applicants are encouraged to review the rubric, PCORI's PCOR Engagement Principles (noted in the rubric), and [PCORI's Methodology Standards Associated with Patient-Centeredness](#).¹⁴ PCORI has also developed a [Financial Compensation](#)

¹⁴ Available at <http://www.pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf>



[Framework](#)¹⁵ for patients, caregivers, and patient/caregiver organizations engaged in PCORI-funded research as engaged research partners. The Financial Compensation Framework should guide applicants while developing engagement plans.

Applicants must outline how patients and other stakeholders will participate as partners in various phases of the proposed research. To assist applicants, PCORI provides [sample engagement plans](#)¹⁶ from previously funded projects.

The [rubric](#) and [sample engagement plans](#) are not intended to be comprehensive or prescriptive; instead, they provide a variety of options to incorporate engagement, where relevant, into the research process. Applicants may choose to include some, but not all, activities and may include additional innovative approaches.

While completing the research team and environment (Section E) component, applicants should describe:

- How and why those research sites were selected
- How they relate to the research project
- The resources, facilities, support, and collaborations available to ensure the project's success
- Ways in which the project will benefit from the unique features of the research environment or community involvement
- How sites will work together to ensure that milestones will be achieved
- Institutional and community investment in the success of the research, such as the availability of organized peer groups
- Logistical support, such as administrative management and oversight, and best practices training
- Financial support, such as protected time for research with salary support

Approach to Patient-Centeredness

This component (up to three pages) is included in the Research Justification Template. Describe the plans to evaluate the contribution and impact of the project on the development of the PCORnet Commons and on PCORnet's capacity to support an increasing volume of research in Phase II and beyond.

Dissemination and Implementation Potential

This component (up to two pages) is included in the Research Justification Template. Describe the potential for disseminating and implementing the results of your work within PCORnet (including at the local hospital or clinic level) and across other settings.

¹⁵ Available at <http://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf>

¹⁶ Available at <http://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf>



PCORI is interested in robust research that can be rapidly disseminated and implemented in clinical and community practice, thus facilitating improvements in patients' and other stakeholders' healthcare decision-making. Applications should include a section that describes the potential for impact of disseminating your findings and facilitating their widespread use in practice. Applicants should describe possible barriers to dissemination and implementation of their work within PCORnet CDRNs and PPRNs and across other settings, and any other limitations of the study that may have an impact on the usability of the findings. Please note: We are asking you to describe the *potential* for dissemination and implementation. PCORI does not expect you to budget for dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.

PCORI encourages applicants to think creatively about how to disseminate findings. Many patients and relevant stakeholders do not access information about their disease condition from scholarly journals or from attending scientific meetings. Refer to [PCORI's Methodology Standards](#)¹⁷ and the [Engagement Rubric](#) for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant.

Replication and Reproducibility of Research and Data Sharing

In this component (up to two pages) describe the ability to replicate and reproduce potentially important findings from PCORI-funded studies in other data sets, clinical settings, and/or populations. This assessment is essential to building confidence in the accuracy of these findings. PCORI promotes sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Propose a method for sharing data and appropriate documentation upon request; specifically describe the method by which a de-identified copy of the final data set will be made available within one year after study completion.

As they complete this template, applicants must describe the requirements regarding replication of research findings and reproduction of research findings, found below.

Replication of research findings: This requirement refers to supporting efforts by other researchers to replicate study findings in other patient populations and data sets. It applies to all applicants, regardless of project size.

Applicants must describe a replication plan that accommodates the following:

- Provision of a complete, final study protocol describing the study population, primary and secondary hypotheses to be tested, sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan. The protocol will usually be expected to be delivered to PCORI with the 12-month progress report and always within three months of the

¹⁷ Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf



end of the funding period. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the study's PI.

- Proposed clinical trials or observational studies should be registered at www.ClinicalTrials.gov.
- Proposed evidence synthesis studies should be registered at <http://www.crd.york.ac.uk/prospero/>.

Reproduction of research findings: This requirement refers to reproducing research findings in the same data set by another researcher(s) not affiliated with the applicant's research team. The ability to reproduce important findings from the original data is critical to establishing trust in PCORI findings. Therefore, PCORI will require a data-sharing plan (described below). Although the plan described below is required of all applicants, subsequent data sharing would be requested by PCORI only after review of findings and a decision that the findings warrant the expense and time of data sharing.

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. We may request that awardees prepare documentation to accompany their final data sets – documentation that enables others in the research community to use the data for additional or secondary analysis – and to make the data and documentation available upon request.

The data-sharing plan must:

- State how a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses will be made available
- Propose a method by which investigators will make this data set available, if requested
- Propose a budget that would cover costs of data sharing, if requested

Note: Do not include this plan in the proposed budget of your application. Depending on the nature, uses, and potential impact of the study findings, PCORI will consider whether incremental funding will be made available to assist investigators in complying with data-sharing requests.

Protection of Human Subjects

In this component (up to five pages) 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, please see Section 5 “Human Subjects Research Policy” from the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),¹⁸ issued by the U.S. Department of Health and Human Services (HHS). Please refer to the [Required Education of Key Personnel on the Protection of Human Subject Participants](#) requirement, below, as you complete this section.

¹⁸ Available at <http://grants.nih.gov/grants/funding/424/supplementalinstructions.docx>.



Consortium Contractual Arrangements

In this component describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables, in accordance with the milestone schedule.

Please keep the following in mind as you complete this section:

- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontracted organizations that will be involved in this project are aware of your organization's subcontract agreement policy and that all involved organizations are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.
- If applicable, subcontractor personnel should be included under key personnel.
- Budget information for subcontracted organizations should 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 Research Justification Template. Throughout the entire research justification, 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 as that in which they appear in the publication), the article title, journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. *References should be limited to relevant and current literature.* It is important to be concise and to select only those literature references pertinent to the proposed research, so that the 10-page limit is not exceeded. Websites should be referenced in the standard URL format (i.e., <http://www.pcori.org>) with the date on which the link was last accessed.

Appendix (Optional)

This component (up to 10 pages) is included in the Research Justification Template. Applicants may provide additional materials that support the proposed study (e.g., survey instruments, interview guides). *Note that Merit Review Officers (MROs) are not required to evaluate this section.*



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-investigator, or other significant contributors), copying the tables provided in this section as needed.

Please note that you may submit a National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient or stakeholder partners serving as key personnel may choose to fill out a patient/stakeholder partner biosketch in lieu of the professional profile/biosketch. At a minimum, each profile must include: the person's name, title, and degrees; each profile or biosketch may be no more than five pages. 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. The backgrounds; relevant experiences related to large data infrastructure projects, to patient and stakeholder engagement, and to the conduct or support of comparative effectiveness research (CER); and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is best poised to complete the work. Applicants should demonstrate that the study team's experience, leadership approach, governance, and organizational structure are appropriate for the project and will serve to achieve the project goals.

Project Performance Site(s) and Resources

This component is included in the People and Places Template. In this section, demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project to plan, within budget, and on time.

Applicants should provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project.

Budget Template

Please complete all required sections and upload the [Budget Template](#) into PCORI Online as a single PDF. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant's PDF budget upload.

Detailed Budget for Each Year of the Project Period

Complete a detailed budget for each year of the project for the prime applicant and any subcontractor(s) proposed in your application. For example, if your study lasts two years, the prime applicant must complete a detailed budget for Year One as well as for Year Two. The subcontractor should follow the same process and complete a detailed budget for each year of the proposed study. An additional personnel form is provided within the template. This additional personnel form should only be used after all the personnel rows for each budget detail year have been completed. Following the example of a two-year study, you may delete the unused Year Three detailed budget and corresponding

additional personnel form from the template. However, you may not add additional years. Maximum project periods are stated in each PFA. Note the following:

A. Personnel Costs

- Personnel Costs: You must include the base salary for each scientific/technical staff member, employee patient or stakeholder partner, or other personnel on your project that are not accounted for in Section B: Consultant Costs.
- PCORI will reimburse for personnel costs that are consistent with and do not exceed what the applicant would normally pay under the institution's 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.
- Compensation: Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. If the application is recommended for funding, the applicant will be required to provide documentation to support the fringe benefits.
- Level of Effort: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all their active funding so it does not exceed 100 percent. Before the application is submitted to PCORI, the AO must certify that all key 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 dedicating effort to the project should be listed on the personnel budget with their levels of effort, even if they are not requesting salary support. Please list the base salary for such persons in the Budget Justification and detailed budget. Before the application can be submitted, the AO must certify that all key personnel will not exceed 100-percent commitment if funded.
- Salary Cap: The PCORI base salary cap for personnel is \$200,000, annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than \$200,000 should 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.
- 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.



Personnel costs must account for the level of effort required to initiate and complete the mandated Peer Review Process.

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 should be included as consultant costs in the budget.
- Provide the total cost of consultant(s), as well as names, expected number of hours, and hourly rate.
- Include the daily consultant fee, travel expenses, nature of the consulting of the effort, and reasons that consultants are required for the proposed project. Note any overlap in duties with personnel. Consultant costs must be reasonable and justified within the Budget Justification.
- Include a letter of support from all consultants, 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 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, or equipment less than \$5,000 per-unit cost. Provide detailed explanations for all costs that exceed \$1,000. You will be asked to provide further detail for each of these costs in the Budget Justification.
- For all supply costs, provide computations for how applicants arrived at the specific number.



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

- Detailed explanation for why the purchase of these items is required to complete the proposed research project
- Statement verifying that the requested items are not currently available for use by the PI
- 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 projected 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 costs should be itemized per trip and be described as either scientific travel or programmatic travel, as outlined below:

- Scientific travel includes travel to present at conferences, symposia, and similar events. Scientific travel is capped at \$10,000 over the life of the project.
- This cap is inclusive of the prime and all subcontractor scientific travel costs.
- Programmatic travel includes travel needed for the conduct of the project (i.e., focus groups, project team, meetings data collection). PCORI closely reviews all travel costs for reasonableness.
- 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.
- For each category of travel (scientific and programmatic), include the number of trips and a brief description of the trips, including the number of people traveling and dates or duration of the stay.
- In the Budget Justification, applicants must provide additional detail to explain the basis for the costs listed and to describe how the travel is directly related to the proposed research project and necessary for achieving programmatic objectives.

E. Other Expenses

- Indicate and include general categories, such as printing, publication, illustration costs, and nonconsulting service contracts when applicable
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include warranties, computer services, data warehousing, or participant incentives.
- In the space provided, include a detailed explanation for items that exceed \$1,000. Applicants must provide further detail for each of these costs in the Budget Justification.

F. Equipment Costs

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



Title to equipment vests with the recipient organization. PCORI, at its discretion, may require applicants to share or transfer equipment to other PCORI-funded projects within the recipient organization. Equipment disposition must be approved by PCORI.

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 PI'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/deliverable they will be supporting on this 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, other expenses, and on \$25,000 of all combined subcontractor costs.
- Applicants who do not have a federally negotiated 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.

In the event that an indirect cost rate agreement is more restrictive than that of PCORI's accepted indirect cost application, PCORI will allow applicant to use the less restrictive rule when calculating indirect costs on submitted budget categories.

Budget Summary for Entire Project

Complete a budget summary of the entire project for the prime applicant and each subcontracted organization. Keep in mind the guidance in the previous section. See [Appendix 2](#) to review acceptable and unacceptable uses of PCORI funding.

Budget Justification

Complete a Budget Justification for the prime applicant and each subcontracted organization for the entire project. Provide sufficient detail to explain the basis for costs and the reason why the costs are necessary to the project.

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

Describe in detail the specific role and tasks each member of the research team will be performing and its impact on the project plan. PCORI will evaluate each member contribution as listed in the Budget Justification to validate meaningful contribution. Provide a clear distinction between individuals who should be considered Key Personnel and those who should be considered 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 it will be available. Use continuation pages as needed.

Letters of Support

Save all letters of support as a **single PDF file** and upload into the PCORI Online System, using the [Letters of Support Table](#) as the first page of the file. To enable easy reference for MROs and PCORI staff, please be sure to follow the guidance below and in the table template. 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 key information being missed by the reviewers. 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 should be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PIs, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations) to your proposed project. Letters of support are not required for such personnel as research assistants, who are not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters of support should clearly reflect the substantive involvement and material contribution to be provided by the signatory parties; they are meant to substantiate the commitment of collaboration of all forms. The quality of the letters—and how they bolster the proposed research—is more important than the number of letters provided.

Please note that PCORI may contact any individuals or organizations included in the letters of support with questions or to confirm support as described in their letters.

Letters of support should be organized in the following manner, noting that they should support the information provided in the research plan:

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the department chair or appropriate organizational official, confirming the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. Also strongly encouraged is a letter from the leadership of your department or organization affirming support to disseminate and implement 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 collaboration from patient and stakeholder partners should clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, goals and outcomes, and so on. Also strongly encouraged are letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for



implementation. Please also include a letter of support for all consultants, 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, signed by the person with approval authority, confirming such access. 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 on the [table](#) and include the page number on which each letter can be found in the single PDF file.

VI. Additional Requirements

Awardees are required to comply with the following requirements:

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

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all key personnel listed in the application. The policy and FAQs are available from the [NIH website](#).¹⁹

PCORI Public Access Policy

PCORI contracts require all awardees to adhere strictly to PCORI's publication policies. These policies will be shared with awardees.

Registering Research Projects

Proposed clinical trials or observational outcomes studies should be registered at [clinicaltrials.gov](#) using the following naming convention: "PCORI-PCORI application number" (e.g., PCORI-XXXX-XXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the [NIH database](#)²⁰ (see "[Data Element Definitions](#)") are required to register. Please also list your registration as a milestone in your application.

Funded clinical trials or observational outcomes studies must be registered at [ClinicalTrials.gov](#).

Funded evidence-synthesis studies must be registered at [PROSPERO](#).²¹ Funded patient registries must be registered at RoPR.²²

¹⁹ Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

²⁰ Available at prsinfo.clinicaltrials.gov

²¹ Available at crd.york.ac.uk/prospéro.

²² Available at patientregistry.ahrq.gov



Standards for Privacy of Individually Identifiable Health Information

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

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The [Office for Civil Rights](#)²³ provides information on the Privacy Rule, including a complete regulation text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts is available at [NIH](#).²⁴

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 contracts negotiations and prior to execution. For more information, please see PCORI’s [Standard Contract 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 study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a PCORI Program Officer in advance.

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

Dissemination and Data Sharing

In accordance with its authorizing legislation, PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding. All recipients of PCORI contracts must agree to these principles and must take steps to facilitate availability of data and samples.

²³ Available at [hhs.gov/ocr](https://www.hhs.gov/ocr)

²⁴ Available at [grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html](https://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html)

Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks, and/or outcomes that occur over the course of each project and that mark progress toward the project's overall aims. 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 successfully within the contract period. Below is a list of milestone examples you may reference as you complete this section of your application:

- Subcontract with a PCORnet data CC, participating CDRN and PPRN study sites, and DSMB, as needed
- IRB approval
- Data cohort identification
- Focus group results
- Interim analyses
- Final analyses
- Data sets, analytic data sets, and codebooks
- Interim progress reports
- Final report
- Manuscripts accepted for publication
- Determination of the appropriate study database and registration (e.g. ClinicalTrials.gov, RoPR, HSRproj, or other)
- Submit results to ClinicalTrials.gov, as applicable
- Draft final report submission
- Respond to PCORI peer review
- Final report acceptance
- Approval of lay/consumer-friendly summary

At the discretion of the PCORI Program Officer, milestones listed above may not be relevant (e.g., recruitment milestones may not be relevant for observational studies).

Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI research contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Because PCORI primarily funds CER, 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, in 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 costs that can be included in a proposed Detailed Budget in 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 stakeholder research study partners) related to their percentage of effort in conducting the research project (such costs should 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 otherwise 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

Costs related to the conduct of the research project must be specifically requested by a funding applicant through itemization on the Detailed Budget and will be considered by PCORI 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:

- In general, 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") will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.







- The willingness of one or more stakeholder groups to cover patient care costs that will be 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 provide an indication that the stakeholder groups will use the research study’s findings. (Such support for the study by a stakeholder group should 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 coinsurance 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 in the implementation or monitoring of 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 study subject data collection and monitoring that would not normally be performed in the course of patients receiving the patient care being evaluated in the research project.

All proposed costs will be reviewed by PCORI. Costs must be deemed allowable, allocable, and directly necessary to 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.

Allowable Costs			Unallowable Costs	
 PERSONNEL SALARIES & BENEFITS	 CONSULTANT FEES	 TRAVEL COSTS	 ADVERTISING	 BAD DEBTS/LOSSES
 EQUIPMENT		 OTHER	 EXCESSIVE AIRFARE	 DONATIONS
 SUPPLIES	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS	 ALCOHOLIC BEVERAGES	 FUNDRAISING
			 ALUMNI ACTIVITIES	 PERSONAL EXPENSES
			 STUDENT HOUSING AND STIPENDS	 LOSSES ON OTHER GRANTS
			 IDLE FACILITIES	 MEMBERSHIPS
			 INTEREST OF BAD DEBTS	 LOBBYING
			 ENTERTAINMENT	 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.

Frequently Denied Budget Items	
	DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)
	DOCKING STATIONS
	DOUBLE MONITORS
	ELECTRONICS PROTECTION PLANS
	OFFICE FURNITURE
	REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD

Appendix 3: Administrative Actions

Applicants who 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 it:</p> <ul style="list-style-type: none"> • Exceeds the specified page limit • Exceeds the specified period of performance outlined in the PFA • Exceeds the maximum budget specified in the PFA • Has adjusted margins or font size • Does not include or has an incomplete Research Strategy 	<p>PCORI will modify an application by removing all pages that exceed stated limits for the following components:</p> <ul style="list-style-type: none"> • Resubmission Letter • Research Strategy • Dissemination and Implementation Potential • Reproducibility and Transparency of Research • Protection of Human Subjects 	<p>Unless the application is automatically rejected or modified, PCORI may request the applicant to submit missing documents or correct non-compliant ones.</p>

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